

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation)	
)	
Defendant.)	
)	

**UNOPPOSED MOTION TO FILE SUBSTITUTE MEMORANDUM IN SUPPORT OF
MOTION FOR SUMMARY JUDGMENT, SUBSTITUTE CONCISE STATEMENT OF
MATERIAL FACTS, SUBSTITUTE OPENING BRIEF ON CLAIM CONSTRUCTION
AND CERTAIN SUBSTITUTE EXHIBITS IN SUPPORT THEREOF**

Defendants Arthrex, Inc. (“Arthrex”) and Pearsalls, Ltd. (“Pearsalls”) (together, “defendants”) discovered minor errors in connection with certain exhibits to the summary judgment and claim construction papers filed on August 11, 2006. Certain of the exhibits cited in defendants’ memorandum in support of their motion for summary judgment, the concise statement of material facts and defendants’ opening brief on claim construction (“the papers”) include excerpts of deposition transcripts. In some instances, a page was inadvertently omitted from the deposition transcript excerpt. In addition, some citations to the exhibits in the papers include references to incorrect deposition transcript pages.

Defendants seek leave to file the following substitute exhibits and papers, being filed concurrently herewith:

i) substitute Exhibits 10, 19 and 28 to defendants' memorandum in support of their motion for summary judgment – the substitute exhibits have been corrected as described below;

ii) a substitute Exhibit 15 to defendants' opening brief on claim construction – the substitute exhibit has been corrected as described below;

iii) a substitute memorandum in support of defendants' motion for summary judgment – the substitute memorandum has been corrected as described below;

iv) a substitute concise statement of material facts – the substitute statement has been corrected as described below; and

v) a substitute opening brief on claim construction – the substitute opening brief has been corrected as described below.

The corrections to the above-identified exhibits and papers are as follows:

In the Exhibits to Defendants' Memorandum in support of their Motion for Summary Judgment:

- 1) Page 345 of Dr. Hermes's deposition transcript was added to Ex. 10.
- 2) Page 79 of Dr. Steckel's deposition transcript was added to Ex. 19.
- 3) Pages 284 and 288 of Dr. Brookstein's deposition transcript were added to Ex. 28.

In the Exhibits to Defendants' Opening Brief on Claim Construction:

- 1) Page 335 of Dr. Hermes's deposition transcript was added to Ex. 15.

In Defendants' Memorandum in support of their Motion for Summary Judgment:

- 1) Page 1, last line and at page 21, line 13, "Ex. 10 at 346:7-10" has been corrected to read --Ex. 10 at 345:7-10--.
- 2) Page 12, line 3, "Ex. 28 at 285:4-10" has been corrected to read --Ex. 28 at 284:4-10--.

3) Page 12, last line, "Ex. 28 at 289:15-23" has been corrected to read --Ex. 28 at 288:15-23--.

In Defendants' Concise Statement of Material Facts:

1) Page 3, Fact 18, the reference to page "346" has been corrected to read --345--.

In Defendants' Opening Brief on Claim Construction:

1) Page 14, line 18, "Ex. 12 at ¶ 27" has been corrected to read --Ex. 11 at ¶ 27--.

2) Page 15, line 1, "Ex. 15 at 336:23-23" has been corrected to read --Ex. 15 at 335:12 - 336:15--.

In accordance with Local Rule 7.1(a)(2), counsel for defendants certify that they conferred with counsel for DePuy Mitek regarding the above-identified corrections on August 16 and 17, 2006, and counsel for DePuy Mitek does not oppose this motion.

Accordingly, defendants move the Court for an Order granting leave to file the above-identified substitute exhibits and papers.

Dated: August 18, 2006

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing UNOPPOSED MOTION TO FILE SUBSTITUTE MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT, SUBSTITUTE OPENING BRIEF ON CLAIM CONSTRUCTION, SUBSTITUTE CONCISE STATEMENT OF MATERIAL FACTS AND CERTAIN SUBSTITUTE EXHIBITS IN SUPPORT THEREOF was served, via the Court's email notification system on the following counsel for Plaintiff on the 18th day of August 2006:

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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a Massachusetts Corporation)	
)	
Plaintiff,)	
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v.)	Civil Action No. 04-12457 PBS
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Arthrex, Inc.)	
a Delaware Corporation)	
)	
Defendant.)	

ORDER

Upon consideration of the Unopposed Motion to File Substitute Memorandum in Support of Motion for Summary Judgment, Substitute Concise Statement of Material Facts, Substitute Opening Brief on Claim Construction and Certain Substitute Exhibits in Support Thereof, it is ORDERED that the motion is GRANTED.

This __ day of August, 2006.

PATTI B. SARIS
UNITED STATES DISTRICT COURT JUDGE

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

V.

Civil Action No. 04-12457 PBS

Arthrex, Inc.
a Delaware Corporation

Defendant.

**SUBSTITUTE MEMORANDUM IN SUPPORT OF DEFENDANTS ARTHREX, INC.'S
AND PEARSALLS LTD.'S MOTION FOR SUMMARY JUDGMENT**

Dated: August 11, 2006

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I. INTRODUCTION

In 2001, defendant Arthrex, Inc. (“Arthrex”) introduced a new suture, called FiberWire, for the orthopedic surgery market. Ex. 1 at 31:2-5. The new suture was more than twice as strong as the sutures conventionally used in orthopedic surgery. Ex. 2 at 8. The key ingredient of FiberWire, a “braided suture,” is ultra high molecular weight polyethylene (“UHMWPE”), one of the strongest synthetic materials that has ever been created. Ex. 3 at § 1.¹ Arthrex’s FiberWire suture was so new and revolutionary that it spawned a new category of suture called “high-strength” suture. Ex. 2 at 2; Ex. 4 at 146:7-14. Arthrex sells FiberWire separately, and it also includes FiberWire as a component of some of its suture anchors.

After seeing the impact of Arthrex’s FiberWire product, plaintiff DePuy Mitek, Inc. (“DePuy Mitek”) realized that without the introduction of its own high strength suture, it would not be able to meet its sales targets. Ex. 5. DePuy Mitek’s original idea was to introduce a “me too” suture that mimicked Arthrex’s FiberWire product. Ex. 5. Eventually, in late 2004, DePuy Mitek introduced its own high strength suture called Orthocord. Ex. 6. DePuy Mitek, however, was not content just to compete in the market. It searched its files to see if it owned some patent that it could assert against Arthrex. Although DePuy Mitek owned no such patents, it located a patent owned by Ethicon, Inc., a sister company that is a part of the Johnson & Johnson empire, and arranged to have the patent assigned to DePuy Mitek to assert it against Arthrex. Ex. 7.

This patent, U.S. Patent No. 5,314,446 (“the ‘446 patent”) (Ex. 8), resulted from a research effort by Ethicon in the late 1980’s and early 1990’s. The ‘446 patent is a paper patent; neither Ethicon nor DePuy Mitek has made a single commercial product under that patent. Ex. 9 at 9-10. Even in the laboratory, Ethicon did not build a sterilized surgical suture that falls within the claims of the patent before the filing date of the ‘446 patent. Ex. 10 at 345:7-10. Despite this

¹ The UHMWPE is braided together with a polyester known as PET.

enormous failure, DePuy Mitek now claims it is entitled to tens of millions of dollars in damages for infringement of this paper patent.

DePuy Mitek's effort to show infringement is a classic example of trying to fit a square peg into a round hole. Unlike Arthrex's FiberWire product, the '446 patent has nothing to do with a high strength suture. Quite to the contrary, the '446 patent, as explained in the specification, involves a combination of materials where a highly pliable and lubricious, but weak, material is added to a stronger material to improve the pliability and handleability aspects of the suture without appreciably sacrificing strength. Ex. 8 at col. 2, ll. 31-37, 62-66; col. 6, ll. 7-8. Even though the resulting suture would be weaker than conventional sutures, the pliability and handling advantages from adding the weak and pliable material outweighs any loss of strength.

Notwithstanding the teachings of the patent, DePuy Mitek asserts that FiberWire infringes. One of the highly pliable and lubricious, but weak, materials identified in the specification is polyethylene, denoted in the claims as "PE." According to DePuy Mitek, the claim term "PE" should be construed to include UHMWPE. The undisputed evidence, however, shows that UHMWPE is extraordinarily strong and a very stiff (non-pliable) material. Ex. 11 at ¶ 56; Ex. 12 at 306:20-307:4. As explained in more detail in the accompanying *Markman* brief ("*Markman Br.*"), DePuy Mitek can only make this argument by putting on blinders and ignoring the patent specification as well as the fundamental differences (e.g., function, molecular weight and molecular structure) between UHMWPE and the long known general purpose PE which had been used in sutures and other materials for decades. Ex. 13 at col. 11, l. 26. In sum, the term PE should properly be construed to exclude UHMWPE and accordingly, there is no infringement.

There is a second, independent reason why there is no infringement. The claims of the '446 patent all include the transitional phrase "consisting essentially of." As in all patent claims, the accused device must meet each and every limitation of the claim. But unlike many patent claims, there is no infringement of a "consisting essentially of" claim if the accused product includes additional ingredients that materially affect the "basic and novel characteristics" of the claimed invention. Here, Arthrex's FiberWire suture includes a coating. Ex. 14. The undisputed evidence in this case, including Ethicon's patents, a patent of DePuy Mitek's expert and the testimony of every relevant witness in this case, is that such coatings are added to sutures to improve the handleability aspects of the suture, especially the "knot tie down" characteristics of the suture. The inclusion of the coating on FiberWire is the death knell to any infringement claim. The stated purpose of the '446 patent was to improve the handleability aspects of the suture. Accordingly, the Arthrex coating affects the basic and novel characteristics of the claimed invention and thus, there is no infringement.²

Apart from the infringement inquiry, the claims of the '446 patent are invalid, particularly if the term "PE" is construed to include UHMWPE. As we show below, the prior art Chesterfield patent, U.S. Patent No. 5,318,575 ("the '575 patent") (Ex. 15), anticipates the claims of the '446 patent because every limitation of the claims is disclosed in that prior art patent (if the term "PE" is construed to include UHMWPE). DePuy Mitek's principal contention seems to be that the '575 patent is not prior art because Ethicon actually reduced its invention to practice before the filing date of that patent. The undisputed evidence, however, belies DePuy Mitek's contention. Ethicon built only a braid (which itself had significant problems), but never

² Arthrex has several other non-infringement arguments, but the above-identified arguments are its principal non-infringement contentions.

built a sterilized suture as required by the claims of the '446 patent. Accordingly, the '575 patent anticipates the claims of the '446 patent.³

II. STATEMENT OF FACTS

A. THE RELEVANT COMPANIES

Arthrex, a privately held Delaware corporation, develops and sells medical products in the field of arthroscopic surgery. Ex. 16. FiberWire is one such product. Pearsalls, a United Kingdom company, is a braid manufacturer. Pearsalls manufactures braids that eventually become FiberWire suture. DePuy Mitek, a Massachusetts corporation, and a Johnson & Johnson company, makes and sells medical products. Ex. 17. Ethicon, also a Johnson & Johnson company, makes and sells suture and was the original owner of the '446 patent. Ex. 18

B. ETHICON'S DEVELOPMENT WORK

Ethicon began the work that led to the '446 patent in 1988. As explained by inventor Steckel, this work was part of a larger project designed to examine possible suture improvements. Ex. 19 at. 103:23-104:17. At the time, the standard braided suture was a product called Ethibond, a suture made entirely of PET polyester which was braided to form the suture. Ex. 4 at 135:4-7.

Dr. Steckel's idea was to braid together two different substances, one to maintain as much of the strength of the suture as possible and the other to enhance the pliability (that is, bendability) and handleability of the suture. As Dr. Steckel explained, the goal was to produce a suture which maintained the strength of Ethibond (made of PET), while having the feel and pliability of silk, a substance known to be very pliable and easy to use. Ex. 19 at 103:23-104:17.

³ There are other prior art combinations that render the asserted claims of the '446 patent invalid for obviousness pursuant to 35 U.S.C. § 103, and the '446 patent is invalid for failing to meet the written description and enablement requirements of 35 U.S.C. § 112. These issues are not raised by this motion for summary judgment. Similarly, Ethicon committed inequitable conduct during the prosecution of the '446 patent which renders the patent unenforceable. This issue also is not raised by this motion.

In early 1989, Dr. Steckel built and tested several braids, although he did not build a sterilized suture, as set forth in the claims of the '446 patent. Ex. 19 at 225:5-8.⁴ Ethicon never built a sterilized suture before the filing date of the '446 patent. Ex.10 at 346:7-10. The braids that Dr. Steckel tested were made of PTFE (commonly known as Teflon) and PET (the polyester material used in Ethibond). Ex. 21 at DMI 2635-38. PTFE is a relatively weak substance, but is lubricious and quite pliable. PET, on the other hand, is a strong substance which gives the suture acceptable strength to avoid breakage. Ex. 8 at col. 4, ll. 33-40. While the resulting braid was not as strong as the all-PET control braid, Dr. Steckel observed that the increases in pliability (resulting from the lubricious PTFE) outweighed the loss of strength (caused by mixing the PET with the weaker PTFE). Ex. 8 at col. 8, ll. 36-49. Dr. Steckel observed that the prototype composite braid "ranked better than the silk and Ethibond in knot tie-down *even without a coating.*" Ex. 21 at DMI 2666. [Emphasis added.]

C. THE '446 SPECIFICATION AND PROSECUTION HISTORY

Three years after Dr. Steckel tested the braids, Ethicon filed the patent application that lead to the '446 patent. Ex. 8 at cover page. A full explanation of the '446 patent specification and prosecution history is included in the accompanying Markman brief (*see Markman Br.* at 2 - 6) and is summarized here as it relates to this motion. The specification teaches several things. First, lubricious yarns are too weak to use alone; that is, the suture would break. Ex. 8 at col. 2, ll. 22-25; col. 4, ll. 50-54; Table. Second, the lubricious yarns are highly pliable, that is, they are very easy to bend. Ex. 8 at col. 2, ll. 22-25; col. 4, ll. 11-14; Table. Third, using two different materials braided together is designed to improve the handleability and pliability aspects of a suture without significantly sacrificing the overall braid strength. Ex. 8 at

⁴ Even here, the braids had considerable problems of "core popping," a problem exacerbated by the difficulties presented by attempting to braid together two different materials. More than a year later, Ethicon observed that the problem had not been solved. Ex. 20. There is no evidence that the problems were ever solved. Ex. 19 at 251:24-252:5.

col. 2, ll. 31-37; ll. 62-66; col. 4, ll. 11-40; col. 6, ll. 7-8. Fourth, while adding coating to a braid is helpful for knot tie down (a handleability characteristic), it creates problems with pliability (as well as added costs). The use of coating can be avoided, and the downsides it brings can be eliminated if a sufficient amount of the lubricious material is used. Ex. 8 at col. 6, ll. 5-17.

The pertinent aspects of the prosecution history can be summarized as follows. As originally filed, the application included claims directed toward “braids” and others directed toward “sutures.” Ex. 22 at 18-20. In response to the Examiner’s assertion that “braid” claims and “suture” claims were different, Ethicon agreed only to prosecute the suture claims. Ex. 23 at 3. In response to a rejection of the claims based on the U.K. patent application to Burgess (“the Burgess application”), Ethicon argued that the qualities of UHMWPE would lead to a poor suture, a clear assertion that Ethicon did not believe that UHMWPE was a material that fell within the patent claims. Ex. 24 at 2-4. In addition, the claims were amended during prosecution to limit significantly the scope of the claims. The transitional phrase “comprising” was amended to “consisting essentially of,” a significantly narrower claim. Ex. 25 at 1. The claims were also narrowed by abandoning the requirement that the suture may be made of two “dissimilar yarns” and instead requiring that the two yarns be from a two lists of specified materials (one from each list). Ex. 25 at 1.

In the claims, seven polymers are identified as the yarns in the first group, of which “PE” is one. As explained in the specification, these materials are lubricious and highly pliable, but are too weak to be used alone. Ex. 8 at col. 2, ll. 22-25; col. 4, ll. 9-32, 50-54; Table. Three materials, PET, nylon and aramid, are identified in the second group. According to the specification, these materials are added to strengthen the suture. Ex. 8 at col. 4, ll. 33-40. Notably, the term PE is never associated with the “strength” yarns.

D. ARTHREX'S DEVELOPMENT OF FIBERWIRE

In the late 1990's, Arthrex investigated the development of a new suture product.⁵ Its motivation was to develop a suture much stronger than existing sutures in the market, one which would be less likely to break when used in orthopedic surgery. Ex. 26 at 44:13-46:9. The original idea was to make a braided suture entirely of UHMWPE, a material known for its incredible high strength. Ex. 26 at 44:13-46:9. While the prototypes met the strength criteria, there were some problems. The suture was too stiff, that is, it lacked pliability, and was difficult to use. Ex. 12 at 306:20-307:4. In addition, while the knots were strong and did not break, the knots had a tendency to slip, making it difficult to secure the knot. Ex. 26 at 46:7-9. The solution was to add PET (the polyester that was used in existing sutures) to the suture braid. The PET was added to provide better flexibility to the suture and to improve the knot security of the suture. Ex. 26 at 68:25-69:21. FiberWire also adds a coating to improve the ability for the knot to slide down the suture and other handleability aspects of the suture. Ex. 14.⁶ Arthrex introduced FiberWire as a stand alone product in August 2001 and eventually began offering FiberWire as an option on most of its suture anchor products. Ex. 27.⁷

III. ARGUMENT

A. STANDARDS FOR SUMMARY JUDGMENT

Summary judgment is appropriate if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a

⁵ At the time, Arthrex did not sell suture as a separate product. It did attach sutures, which it bought from an outside vendor, to the suture anchors that it sold.

⁶ As an added benefit, the coating improves the strength of the knot and the pliability of the suture.

⁷ Arthrex also sells variants of FiberWire, called TigerWire and FiberStick. For the purposes of this motion, the differences between the products is not relevant. Accordingly, the term "FiberWire" in this motion includes FiberWire and its variants.

matter of law. *Q-Pharma, Inc. v. Andrews Jergens Co.*, 360 F.3d 1295, 1299-1300 (Fed. Cir. 2004). The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor. *Id.*

The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. *Matsushita Elec. Indus. Co., Ltd. v. Cinram Int'l, Inc.*, 299 F.Supp.2d 348, 357 (D. Del. 1994) (citing to *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986)). If the nonmoving party fails to make a sufficient showing of an essential element of its case with respect to which it has the burden of proof, then the moving party is entitled to judgment as a matter of law. *Id.* (citing to *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)). In other words, the court must grant summary judgment if the party responding to the motion fails to make a sufficient showing on an essential element of his case with respect to which he has the burden of proof. *Id.* at 357.

B. FIBERWIRE DOES NOT INFRINGE THE ASSERTED CLAIMS OF THE '446 PATENT

To establish infringement, the plaintiff must show that the accused product has each and every limitation of the asserted claim either literally or by the doctrine of equivalents. *See, e.g., Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1273 (Fed. Cir. 2004). If even a single limitation is missing in the accused product, there is no infringement.

MicroStrategy, Inc. v. Business Objects, S.A., 429 F.3d 1344, 1352 (Fed. Cir. 2005). Claim 1, cited in full below,⁸ is an independent claim. The other asserted claims, claims 2, 8, 9 and 12,

⁸ Claim 1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

are dependent claims, that is, they include all the limitations of the independent claim (here claim 1) plus additional limitations. Since the two infringement defenses presented in this motion relate to limitations in the independent claim, they also relate to limitations in the dependent claims.

There are at least two reasons why there is no infringement of the asserted claims. First, the FiberWire product does not have “PE,” as that term should be construed within the patent. Second, the addition of coating to the FiberWire product eliminates any possibility of infringement because coating affects the basic and novel characteristics of the ‘446 patent.

1. The UHMWPE in FiberWire is not a yarn from the first set from the group consisting of PTPE, FEP, PFA PVDF, PETFE, PP AND PE
 - a. There is no literal infringement

The infringement inquiry is a two part process. First, the claim terms must be properly construed and second, a determination must be made whether the accused device has the properly construed limitations. *Dynacore Holdings*, 363 F.3d at 1273. There is no dispute that FiberWire contains UHMWPE. It is DePuy Mitek’s position that UHMWPE constitutes “PE” and thus, the “yarn from the first set” limitation is met. But as we show in our *Markman* brief, the proper construction of “PE” excludes UHMWPE. *See Markman Br.* at 10-16. Should the Court agree, then there is no dispute that FiberWire does not contain any of the identified “yarn[s] from the first set” and accordingly, there is no literal infringement of the asserted claims.

- b. There is no infringement under the doctrine of equivalents

DePuy Mitek contends that even if this Court construes the term “PE” to exclude UHMWPE, there is still infringement under the doctrine of equivalents. Infringement by

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid, and c) optionally a core.

equivalents is a limited doctrine designed to prevent “[o]ne who seeks to pirate an invention [by making] minor variations to conceal and shelter the piracy.” *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605 (1950). Application of the doctrine of equivalents should be the exception, not the rule because, if the doctrine becomes simply the second prong of every infringement charge, claims will cease to serve their intended notice purpose. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed Cir. 1991). Accordingly, infringement by equivalents can only be found if the differences are insubstantial. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 24 (1997).

The doctrine of equivalents is further limited by the “all elements” rule. This means that equivalents must be applied to individual elements of the claim rather than to the invention as a whole. *Id.* at 18.⁹ Thus, the question is whether the differences between UHMWPE and the first set of yarns is insubstantial. Unless that test is met, there can be no equivalents.

The undisputed facts show that UHMWPE is not equivalent to the materials identified in the first set of yarns. Indeed, for the same reasons that UHMWPE does not fall within the meaning of PE, UHMWPE cannot be considered an equivalent. The first set of yarns constitute lubricious yarns included in the braid “to improve overall pliability” of the suture. Ex. 8 at col. 4, ll. 12-13. A braid made solely of such lubricating yarns is described as “highly pliable.” Ex. 8 at col. 2, ll. 23-24. UHMWPE is stiff (Ex. 12 at 306:20-307:4) and as DePuy Mitek’s expert admits, a braid made of only UHMWPE is too stiff (Ex. 11 at ¶ 56) – the polar opposite of what is described in the ‘446 patent.

⁹ The doctrine of equivalents is further limited by prosecution history estoppel which, except under limited circumstances, prevents a finding of equivalents if the claim limitation was amended. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd.*, 344 F.3d 1359, 1366 (Fed. Cir. 2003). Here, the first set of yarns limitation was added by amendment, so prosecution history estoppel precludes a finding of equivalents. This issue, however, is not presented by this motion.

Likewise, the admitted purpose of using UHMWPE in FiberWire is to add strength to the braid (Ex. 11 at ¶ 56; Ex. 28 at 290:19-25). In the '446 patents, the purpose of the first set of yarns is to improve pliability and handleability. It is the second set of yarns that imparts strength in the '446 patent.

Finally, the '446 patent teaches that lubricating yarns are "relatively weak." Ex. 8 col. 2, l. 25. In the tradeoff between braid strength and pliability, the '446 patent accepts the fact that the first set of yarn will somewhat weaken the braid because the increases in pliability from the first set of yarns will outweigh the loss of strength. Ex. 8, col. 2, ll. 26-28, 31-37; col. 8, ll. 19-49. The undisputed facts are that UHMWPE is strong, not weak. In light of these undisputed differences, the only possible conclusion is that the differences between the first set of yarns and UHMWPE is not insubstantial and accordingly, there can be no infringement by equivalents.

DePuy Mitek's attempts to create an equivalent argument where one does not exist through the report and testimony of its expert, David Brookstein. Dr. Brookstein uses a "function, way, result" test¹⁰ and concludes that UHMWPE is equivalent to the first set of yarns.¹¹ The function, way, result test is met if the function, way and result set forth in the patent for the limitation at issue (here, the first set of yarns) is the same as the function, way and result of the alleged equivalent material (UHMWPE). *Upjohn Co. v. Mova Pharmaceutical Corp.*, 225 F.3d 1306, 1309 (Fed. Cir. 2000).

The analysis that Dr. Brookstein sets forth, however, bears no relationship to the claims. For example, according to Dr. Brookstein, "[t]he function of the first set of yarns is to

¹⁰ The function, way result test can be used to decide the equivalents issue in appropriate cases. *Warner-Jenkinson*, 520 U.S. at 39-40.

¹¹ Dr. Brookstein could not decide at his deposition whether UHMWPE should be compared to the first set of yarns or just to PE. Ex. 29 at 276:11-15; 279:1-20. His report, however, makes the comparison to the first set of yarns.

contribute a property that is different from the second set.” Ex. 11 at ¶ 54. But Dr. Brookstein was forced to admit that *any* material would meet his functional identify as long as it contributed *anything* to the suture different from the second yarn. Ex. 28 at 284:4-10. Just to state the proposition is to demonstrate the absurd and unsupportable nature of the Brookstein test.

The simple fact is that the Brookstein recitation of function bears no relationship to the function of the first set of yarns set forth in the claims, as the law requires. The first set of yarns is comprised of the seven specific materials set forth in the claims. The patent leaves no doubt that a function of those materials is “to improve the overall pliability” of the braid. Ex. 8 at col. 4, ll. 12-13. The UHMWPE in FiberWire, of course, does not serve that function. It cannot because, as even Dr. Brookstein admits, it is too stiff. Ex. 11 at ¶ 56.¹² On this basis alone, the Brookstein analysis is fatally flawed.¹³

The prosecution history of the patent further reveals the flaw in Dr. Brookstein’s analysis. As the application was originally filed, it included broad claims which required only that there be two dissimilar yarns in direct intertwining contact. These original claims did not identify any specific materials. Ex. 22 at 18-20. But Ethicon abandoned these claims and instead only pursued the narrower claims which did identify the specific materials in each set of yarn. Ex. 25. While an argument could be made that Dr. Brookstein’s function and result have some relationship to these broad, abandoned claims, his analysis simply ignores the fact that these claims are not the claims at issue here. Dr. Brookstein admitted that he never considered the prosecution history in performing his function, way, result test. Ex. 28 at 288:15-23. If he

¹² Indeed, even Dr. Brookstein admits that the “flexibility,” *i.e.*, pliability function is served by the PET, not UHMWPE, in FiberWire. Ex. 11 at ¶ 64; Ex. 28 at 300:24-301:15.

¹³ Dr. Brookstein’s analysis of the “result” comparison suffers from the exact same problem. Ex. 11 at ¶¶ 61-63.

had, he would have realized that the function and result set forth in his report have no relationship to the function and result of the first set of yarns, as claimed in the '446 patent.

2. The Addition of Coating to FiberWire Avoids Infringement Because Coating Affects the Basic and Novel Characteristics of the '446 Patent

Patent claims typically include a transition phrase between the preamble of the claim and the rest of the claim. Most often, that transitional phrase is “comprising.” This means that the patent claim is “open”, that is, infringement is not avoided where the accused device includes materials in addition to those identified in the claim. *See, e.g., Free Motion Fitness, Inc. v. Cybex Intern, Inc.*, 423 F.3d 1343, 1353 (Fed. Cir. 2005). Unlike the phrase “comprising,” the phrase “consisting essentially of” in a patent claim is not an open term. Infringement is avoided if the accused device contains additional ingredients that materially affect the basic and novel properties of the claimed invention. *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003). In this case, it is undisputed that FiberWire includes a coating, and that coating is not a listed item in the asserted claims. Thus, the sole issue is whether coating materially affects the basic and novel characteristics of the claims of the '446 patent. The undisputed facts show that it does and accordingly, there is no infringement.

The first step is to define the basic and novel characteristics of the claims of the '446 patent. This issue is discussed in detail in the *Markman* brief. *See Markman Br.* at 16-18. The second step is to determine whether coating materially affects those basic and novel characteristics.¹⁴ As we show below, the undisputed facts are that it does.

As shown in our *Markman* brief, the basic and novel characteristics of the claims of the '446 patent is having two dissimilar yarns braided together to achieve improved handleability or pliability without significantly sacrificing its physical properties. *See Markman Br.* at 16-18.

¹⁴ An effect on the basic and novel characteristics of the claimed invention is material if the affect is of importance or of consequence to those of ordinary skill in the art. *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998).

The evidence overwhelmingly and undisputedly shows that coating materially affects the handleability aspects of the suture,¹⁵ particularly the knot tie down characteristics.¹⁶

That coating affects handleability characteristics of the braid, including knot tie-down, is so well known in the suture art that it hardly bears citation.

(1) Ethicon patent after Ethicon patent, including patents of Alistair Hunter, one of the inventors of the '446 patent, make that statement. *See* Ex. 34, col. 1, ll. 14-18 (“a multifilament suture typically requires a surface coating to improve the tactile smoothness, pliability and tiedown performance of the suture”); Ex. 35, col. 1, ll. 11-15 (same); Ex. 36, col. 1, ll. 12-15 (“multifilament suture typically require a surface coating to improve the pliability and knotting characteristics of the suture”).

(2) A patent of Dr. Matthews Hermes, one of DePuy Mitek’s experts in this case, makes the same assertion. Ex. 37, col. 1, ll. 19-25 (“It has therefore become a common practice to coat sutures, particularly those of the multifilament variety, with compositions which improve their knot tie-down performance and perhaps one or more other properties of the sutures as well”).

¹⁵ There is also significant evidence that coating affects the pliability of the suture as well as knot strength. Those issues, however, are not raised by this motion.

¹⁶ As Ethicon’s own Wound Closure Manual explains, knot tie down is the ease by which a knot slides down the suture. Ex. 29. A drawback of a braided suture is that it can be relative rough. As a result, when a surgeon slides a knot down the suture, the roughness may cause some “chatter” making it more difficult to tie a knot. Ex. 30 at col. 1, ll. 43-54. As DePuy Mitek and Ethicon witnesses observe, knot tie down is a well known suture handleability characteristic. Ex. 31 at 165:16-166:3; Ex. 32 at 94:19-95:6; Ex. 19 at 79:19-23. In fact, the '446 patent itself recognizes knot tie down as a handleability characteristic of a suture. Ex. 8 at col. 6, ll. 5-7.

Likewise, other known handleability characteristics include tactile feel, compliance, tissue drag, knot security, knot stability, coefficient of friction, stiffness, softness, smoothness, lack of chatter, tissue abrasion and lie-down of the knot. Ex. 33 at 20.

(3) Ethicon's Wound Manual makes the same point. Ex. 29 at 11 ("Multifilament sutures may also be coated to help them pass relatively smoothly through tissue and enhance handling characteristics.").

(4) Articles in the field concur. *See* Ex. 28 at 525 ("synthetic sutures have been coated to decrease their coefficient of friction and improve their handling characteristics.").

(5) Ethicon and DePuy Mitek observed that coating affects handleability when developing its Orthocord product (which competes directly with FiberWire) and other suture products. *See, e.g.*, Ex. 39 (Orthocord is coated "for improved slide ability and enhanced knot tying characteristics (*e.g.* knot slide)."); Ex. 40 ("The purpose of coating the Panacryl suture is to provide the suture with handling properties.").

(6) Every DePuy Mitek and Ethicon witness who testified on the subject agreed. Ex. 4 at 64:12-24; Ex. 41 at 48:11-49:2; Ex. 31 at 167:1-13; Ex. 18 at 295:23-296:7; Ex. 42 at 63:10-23.¹⁷

In light of this overwhelming evidence, it comes as no surprise that Arthrex's documents confirm that coating is added to improve handling characteristics. *See* Ex. 14 ("The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue). And if there were any doubt – and there is absolutely none, the '446 patent itself confirms that coating is added to improve handling characteristics of the suture, including knot tiedown *See* Ex. 8 at col. 1, ll. 29-31 ("multifilament sutures almost universally possess a

¹⁷ Incredibly, the only witness who did not readily agree was Dr. Brookstein, DePuy Mitek's so-called suture expert. When confronted with this overwhelming evidence, Dr. Brookstein's meek response was that had not reviewed the material (although he had had the opportunity to do so) and that he simply does not know if this is the known purpose of adding a coating. Ex. 28 at 167:14-169:6. The only conclusion that can be drawn from his testimony is either that Dr. Brookstein is not an expert on suture coating (a likely conclusion because he testified that he only worked on one suture project in his professional life and he did not remember if it involved issues of coating (Ex. 28 at 165:16-166:4)) or Dr. Brookstein simply cannot be believed.

surface coating to improve handling properties.”); col. 6, ll. 5-8 (“If desired, the surface of the heterogeneous multifilament braid can be coated . . . to further improve the handleability and knot tiedown performance of the braid.”).

In short, the evidence is overwhelming and cannot be disputed. Coating affects the handleability of the suture – the same suture improvement that the ‘446 patent purports to achieve by its invention. Since the undisputed facts are that coating is added to FiberWire and coating materially affects the basic and novel characteristics of the claimed invention, there is no infringement.¹⁸

DePuy Mitek has no answer to this daunting evidence, so it incorrectly tries to change the question. According to its expert Dr. Brookstein, DePuy Mitek argues as follows: FiberWire was designed to have the two different yarns – UHMWPE and PET – contribute different properties to the braided suture. The contribution of different properties is present both before and after coating is added. Therefore, coating does not materially affect the basic and novel characteristics of the claimed invention. Ex. 44 at ¶ 24. DePuy Mitek comes to the same conclusion both under its and defendants’ view of the basic and novel characteristics of the claimed invention. Ex. 44 at ¶ 23.

¹⁸ The result is no different if the court were to accept DePuy Mitek’s view of the basic and novel characteristics of the claimed invention. According to DePuy Mitek, the basic and novel characteristics are “a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. *See* Ex. 11 at ¶ 27; *see also* Ex. 44 at ¶ 28. As we understand DePuy Mitek’s position, it does not matter what property each yarn contributes to the suture, an added, unlisted material – here coating – affects the basic and novel characteristics as long as it affects the same suture property as one of the yarns.

PET is one of the yarns of the FiberWire braid. As DePuy Mitek itself contends, one of the purposes of the PET is to improve the knot tying ability of the suture braid. *See* Ex. 45 at ¶ 15. As shown above, this is one of the precise purposes of coating a suture. *See supra* at 13-16. Accordingly, even under DePuy Mitek’s view of the basic and novel characteristics of the claimed invention, coating has a material effect and its inclusion in FiberWire precludes a finding of infringement.

Stated another way, Dr. Brookstein asserts that coating does not affect the basic and novel aspects of the claimed invention because “the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided.” Ex. 44 at ¶ 27. When asked what this means, Dr. Brookstein replied that coating could only affect the basic and novel characteristics if “the coating in some *miraculous* way made those materials not yarns anymore” or “all of a sudden you had a set from A, a set from B and now it was some magical structure that wasn’t yarns, it wasn’t two sets, they were all the same, that would be a transformation.” Ex. 28 at 399-400, emphasis added. Just to state the proposition shows its absurdity. In DePuy Mitek’s and Dr. Brookstein’s world, only “magic” and “miracles” can cause an added material to affect the basic and novel characteristics of an invention. That plainly is wrong.

The most that could be said of DePuy Mitek’s position is that it believes that an added material that improves the basic and novel characteristics can never materially affect those characteristics, no matter how much the improvement. Indeed, Dr. Brookstein opined that coating could never affect the basic and novel characteristics even if it “improves one of the properties that one of the materials contributes to the braid.” Ex. 28 at 211:7-14. But the law is to the contrary. The Federal Circuit acknowledged that an added material can affect the basic and novel characteristics of an invention even if it only serves to improve those characteristics. *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1246 (Fed Cir. 2001) (citing witness testimony that barrier layers are necessary for operation of accused product). *See also, Bayer A.G. v. Sony Electronics, Inc.*, 228 F. Supp.2d 332, 346-47 (D. Del. 2002) (stating that presence of cobalt materially affected the basic and novel properties of the claimed invention while citing witness testimony that the affect was to improve those properties); *Binney & Smith v. Rose Art Indus., Inc.*, 1995 U.S. Dist. LEXIS 2602 at *30 (N.D. Ill. 1995) (in denying injunctive relief due

to unlikelihood of success on infringement, court cited advantages of large volume of silicon dioxide in accused product as potential material affect); *American Machine & Foundry Co. v. Liggett & Myers Tobacco Co.*, 172 F. Supp. 12, 19 (D. N.J. 1959) (stating improvements in water resistance were material affect of basic and novel characteristics).

DePuy Mitek's second argument is that coating cannot affect the basic and novel characteristics of the claimed invention because the '446 patent says that "if desired, the surface of the . . . braid can be coated . . . to further improve the handleability and knot tiedown performance of the braid." Ex. 44 at ¶ 33. Depuy Mitek is wrong for several reasons. The short answer is that the law is to the contrary. In *AFG*, just like here, the patent stated that certain materials could be added. *AFG*, 239 F.3d at 1242. Notwithstanding that disclosure, the Federal Circuit acknowledged that use of such unlisted materials could materially affect the basic and novel characteristics of the invention. *AFG*, 239 F.3d at 1247. *See also, American Machine*, 172 F. Supp. at 19 (although additional substances were disclosed in specification, they were not in claims and could materially affect basic and novel characteristics).

Even if DePuy Mitek's argument had applicability in some circumstances, it would not apply here. As explained above, the claims, as originally submitted did not contain the "consisting essentially of" transitional phrase. Rather, the transitional phrase in the original claims was "comprising." For a "comprising" claim, it is no defense that the accused product has additional unlisted materials. *Free Motion*, 423 F.3d at 1353. Accordingly, it makes perfect sense, as the application was originally filed, that the patent would state that coating could be used, particularly because the patent recognizes that the coating improves certain handleability aspects of a suture. But once the transitional phrase "consisting essentially of" was added to the claim, which in turn narrowed the claim, DePuy Mitek's rationale falls apart.

Finally, an accurate reading of this passage of the patent shows that it supports *defendants'* position, *not* DePuy Mitek's. The passage asserts that coating improves suture handleability and knot tiedown, itself an *admission* that coating affects the basic and novel characteristics. The passage goes on to say that "if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricious yarn system, *the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening*." Ex. 8 at col. 6, ll. 13-17, emphasis added. That the patent teaches it is best to "eliminate[]" and "avoid[]" coating is graphic proof that its use in the accused product should lead to a finding of no infringement. *See, e.g., On Demand Machine Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1340 (Fed. Cir. 2006) (claims may be construed to exclude a feature criticized in the specification).

For all the foregoing reasons, use of coating in FiberWire affects the basic and novel characteristics of the patent and, as a result, there is no infringement.

C. IF THE COURT CONSTRUES PE TO INCLUDE UHMWPE, THE '446 PATENT IS INVALID AS ANTICIPATED BY THE '575 PATENT

As explained in detail in Defendants' *Markman* brief, properly construed, the claim term "PE" means a general purpose polyethylene and does not include UHMWPE. If, however, the Court were to determine that the claim term PE does include UHMWPE, then the '446 patent is invalid as anticipated by the '575 patent.

A patent claim is invalid for anticipation where a single prior art reference discloses every limitation of the patent claim. *See, e.g., Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1321 (Fed. Cir. 2003). As long as the claimed invention is disclosed within the "boundaries of a single reference," the reference anticipates. *See, e.g., Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1577 (Fed. Cir. 1991). As we show below, the '575 patent is prior art to the '446 patent and, if PE is construed to include

UHMWPE, every limitation of the asserted claims of the ‘446 patent is disclosed within “the boundaries of” the ‘575 patent.

1. The ‘575 patent is prior art to the ‘446 patent

On its face, the ‘575 patent is prior art to the ‘446 patent under 35 U.S.C. § 102(e)(2) since it was filed prior to the filing date of the ‘446 patent.¹⁹ The only way DePuy Mitek can show that the ‘575 patent is not prior art is by providing evidence that it invented the subject matter of the ‘446 patent prior to the filing date of the ‘575 patent (*i.e.*, February 3, 1992). *See e.g., Innovative Scuba Concepts, Inc. v. Feder Indus., Inc.*, 26 F.3d 1112, 1115 (Fed. Cir 1994) (burden of going forward with evidence of prior invention shifts to patentee once evidence of prior art is presented by defendant). In order to show it invented the subject matter of the ‘446 patent prior to the filing date of the ‘575 patent, DePuy Mitek must show that the claimed invention of the ‘446 patent was both conceived of and reduced to practice prior to the filing date of the ‘575 patent. *Id.*

According to its interrogatory answers and its expert submissions, DePuy Mitek argued that it can predate the ‘575 patent because Ethicon conceived of the invention by June 6, 1988 and reduced it to practice by February 1989. The undisputed facts, however, establish that Ethicon did not reduce the invention to practice prior to the date that it filed its patent application.

To establish reduction to practice, DePuy Mitek “must prove that [it] constructed an embodiment . . . *that met all the limitations of the claim*, and that [it] determined that the invention would work for its intended purpose.” *See e.g., Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1265 (Fed. Cir. 2002). [Emphasis added.] *See also, Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998) (“there cannot be a reduction to practice of the invention

¹⁹ The ‘575 patent was filed February 3, 1992, whereas the ‘446 patent was filed February 19, 1992. *Compare* Ex. 15 at cover page, Ex. 8 at cover page.

without a physical embodiment which includes all limitations of the claim”), *Hummer v. Administrator of Nat. Aeronautics and Space Admin.*, 500 F.2d 1383, 1387 (Ct. Cust. & Pat. App. 1974) (“to constitute an actual reduction to practice, the device demonstrated must include every limitation of the claim”) Thus, if even a single claim limitation is missing from what is built, there is no reduction to practice.

The undisputed evidence in this case is that Ethicon, through its inventor, Dr. Steckel, built and tested heterogeneous braids in February 1989. But one of the limitations of the asserted claims is that the product be a *sterilized* suture. The undisputed evidence is that the braids built and tested by Dr. Steckel were not “sterilized.” Dr. Steckel’s notebook makes no mention of sterilization in connection with any work on this project and Dr. Steckel confirmed that the heterogeneous braids he tested were not sterilized. Ex. 19 at 225:5-8. Likewise, Dr. Hermes confirmed that he had no evidence that Ethicon built a sterilized suture before the filing date of the ‘446 patent. Ex. 10 at 345:7-10.

Since, as a matter of law, reduction to practice requires that the embodiment constructed meet *all* the limitations of the claim, and since it is undisputed that the braids constructed by Dr. Steckel were not “sterilized,” a limitation of all the asserted claims of the ‘446 patent, DePuy Mitek can not predate the ‘575 patent by showing an earlier reduction to practice. Accordingly, the ‘575 patent is prior art to the ‘446 patent.

2. The ‘575 patent discloses every limitation of the asserted claims of the ‘446 patent

As explained above (*supra* at 19), a patent claim is anticipated where a single prior art reference discloses every limitation of the claim. As we show below, every limitation of the asserted claims of the ‘446 patent is disclosed in the ‘575 patent.

- a. Independent claim 1 is anticipated by the ‘575 patent

For the convenience of the Court, we break down claim 1 of the ‘446 patent into its various limitations, and then we demonstrate that each limitation is disclosed in the ‘575 patent.

i. A surgical suture consisting essentially of

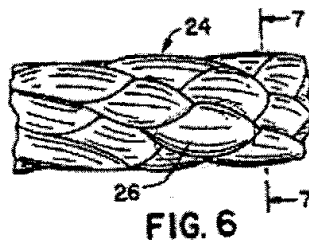
The ‘575 patent discloses a surgical suture. For example, the title of the ‘575 patent itself recites a method of using a “suture product.” Since the ‘575 patent is directed to suture, it should come as no surprise that sutures are disclosed many times in connection with the ‘575 patent specification and drawings. Ex. 15 at col. 2, l. 62; col. 3, ll. 2, 8, 15; col. 7, l. 26, 38, 43, 59.

Incredibly, DePuy Mitek, through its expert Dr. Hermes, tries to raise a factual dispute. Although Dr. Hermes conceded in his report that claim 1 of the ‘575 patent recites “a flexible elongated member,” he stated that it was his “opinion” that this was limited to a sternum closure device and not a suture. Ex. 43 at ¶ 80. But Dr. Hermes simply ignores the disclosure of the ‘575 patent continually describing the elongated member as a suture. Moreover, when confronted with this evidence at his deposition, Dr. Hermes had no choice but to admit that the ‘575 patent does disclose flexible elongated members that are sutures. Ex. 10 at 212:25-213:5. Accordingly, Dr. Hermes’s “opinion” is not supported by any factual basis and cannot create a dispute over a genuine issue of material fact. *See, e.g., Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F.3d 1052, 1080-81 (Fed. Cir. 2005) (without a foundation or basis for an expert’s opinion, that opinion alone does not rise to the level of “genuine issues of fact” to defeat a motion for summary judgment).

- ii. a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

The next limitation of claim 1 of the '446 patent is also disclosed by the '575 patent. For example, claim 1 of the '575 patent recites that "first and second fibers" are "braided to form [an] elongated member." A person of ordinary skill in the art would plainly understand that this is a disclosure of two materials braided together in direct intertwining contact. See Mukherjee Rebuttal Report at 9. Even DePuy Mitek's expert meant "direct intertwining contact" when he used the term "braided" in his own patent. Ex. 45 at col. 2, l. 65 – col. 3, l. 2; Ex. 10 at 170:6-12.

Further, FIG. 6 of the '575 patent (reproduced below) discloses a spiroid braid with several yarns (items 26) that are braided in "direct intertwining contact," according to the construction agreed upon by the parties.



That is, FIG. 6 discloses that there is a "mechanical interlocking or weaving of the individual yarns [items 26] that make up the suture braid." Even Dr. Hermes agreed that FIG. 6 disclosed direct intertwining contact. Ex. 10 at 201:24-202:5.²⁰

DePuy Mitek has not attempted to contest that the vast majority of this limitation is disclosed in the '575 patent. The only aspect with which it attempts to take issue is the requirement that the one yarn from the first set is "in direct intertwining contact" with at least one yarn from the second set. According to DePuy Mitek, through its expert Dr. Hermes, the

²⁰ Furthermore, the disclosure of the '575 patent also acknowledges that the suture products must be sterilized. Ex. 15 at col. 1, line 36 (citing U.S. Patent No. 4,813,416, which discloses the need for sterilization with surgical products).

‘575 patent does not show any “direct intertwining contact” between the two different materials, one from each of the sets of yarns described in the ‘446 patent.²¹

In his report, Dr. Hermes opined that the claims of the ‘575 patent “do not recite that the first and second fibers are in direct intertwining contact, as opposed to a core-sheath arrangement.” Ex. 43 at ¶ 79. But, at his deposition, Dr. Hermes could not provide a single example of a braided construction that was not braided in “direct intertwining contact.” Ex. 10 at 212:25-213:5. Further, when confronted with the spiroid braid in FIG. 6 of the ‘575 patent (reproduced above), Dr. Hermes admitted that it disclosed “direct intertwining contact.” Ex. 10 at 201:24-202:5.

In short, there is absolutely no legitimate factual basis for Dr. Hermes’s opinion. The Federal Circuit has held that without a foundation or basis for an expert’s opinion, that opinion alone does not rise to the level of “genuine issues of fact” to defeat a motion for summary judgment. *Invitrogen*, 429 F.3d at 1080-81. The court also stated that the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment. *Id.* at 1080 (citing the Supreme Court in *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986)). Likewise, here, DePuy Mitek has not raised a genuine issue of material fact.

- iii. a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

²¹ The only other place DePuy Mitek appears to contest the sufficiency of the disclosure of the ‘575 patent is in its response to Arthrex’s interrogatories. There, DePuy Mitek only contends that “Arthrex has failed to cite to a teaching of braided yarns as claimed in the ‘446 patent. Ex. 46. No reasoning or evidence is provided. A conclusion without support cannot raise a genuine issue of disputed fact. *See, e.g. TechSearch, L.L.C. v Intel Corp.*, 286 F.3d 1360, 1372 (Fed. Cir. 2002). Thus, this interrogatory response cannot create a genuine issue of material fact.

This limitation of claim 1 of the '446 patent is also disclosed by the '575 patent. For example, claim 1 of the '575 patent recites that the first fibers are "ultra high molecular-weight high tenacity material." The specification of the '575 patent specifically discloses that the ultra high molecular-weight high tenacity material is UHMWPE. Ex. 15 at col. 2, l. 31.

DePuy Mitek does not dispute this limitation. In fact, Dr. Hermes agreed that "ultra high molecular high tenacity material," as recited in claim 1 includes UHMWPE. Ex. 10 at 197:12-25

- iv. b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

This limitation of claim 1 of the '446 patent is also disclosed by the '575 patent. For example, claim 11 of the '575 patent adds that the second fiber is nylon.

Although the '575 patent need disclose only one of these materials in this limitation to anticipate, it does disclose another material. For instance, claim 12 of the '575 patent adds that the second fiber is polyester.²²

DePuy Mitek does not dispute these disclosures. In fact, Dr. Hermes acknowledged these disclosures in the '575 patent at his deposition. Ex. 10 at 198:7-11, 14-18.

- v. c) optionally a core

Since this last limitation is optional, the '446 patent need not disclose it for the '575 patent to anticipate the '446 patent.

- b. The asserted dependent claims of the '446 patent are anticipated by the '575 patent

²² The specific polyester identified in the '575 patent is Dupont Dacron polyester (*i.e.*, a trade name for PET). Ex. 15 at col. 7.1.63. Moreover, DePuy Mitek's expert Dr. Brookstein asserted that polyester is synonymous with PET to those skilled in the suture art. Ex. 28 at 54:4-9.

The additional limitations added by the asserted dependent claims are also shown in the ‘575 patent.²³ Asserted claim 2 of the ‘446 patent adds that the suture is attached to a needle. The ‘575 patent also discloses the use of a needle attached to a suture. Ex. 15 at col. 5, ll. 41-42.

Asserted claim 8 of the ‘446 patent also adds that the second fiber-forming material is PET. As described, in n. 22, *supra*, the specific polyester identified in the ‘575 patent is Dupont Dacron polyester (i.e., a trade name for PET). Ex. 15 at col. 7, l. 63.²⁴

Asserted claim 9 also adds the PET requirement (the additional limitation from claim 8) and further adds that “the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.” As stated in the *Markman* brief, the parties have agreed that this claim term means that “the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture” ranges from about 20 to about 80 percent.

The ‘575 patent disclose a spiroid braided suture having one or more yarns of UHMWPE where the remainder of the yarns are non-absorbable yarns. Ex. 15 at col. 4, ll. 8-24; FIG. 6. Dr. Hermes agreed that FIG. 6 of the ‘575 patent discloses that more than one yarn (item 26) can be made of UHMWPE with and that one or more of the yarns (item 26) can be a non-absorbable yarn. Ex. 10 at 207:12-21. Since the ‘575 patent discloses that UHMWPE can make up any number of yarns of the suture, the ‘575 patent plainly includes a volume fraction of the first fiber-forming material between about 20-80%.

²³ As stated above, the asserted dependent claims all contain the limitations of claim 1 plus additional limitations. As we demonstrated above, the limitations from claim 1 (included in the dependent claims) are all disclosed by the ‘575 patent.

²⁴ Moreover, claim 12 of the ‘575 patent (Ex. 15 at col. 8, l. 62) discloses that the second fiber-forming material is polyester, a term synonymous with PET. *See supra* at n. 22.

Asserted claim 12 adds both the requirement that the second fiber forming material be PET (the additional limitation from claim 8) and that a needle be attached to the suture (the additional limitation of claim 2). For the same reasons discussed in connection with claim 2 and claim 8, claim 12 is also anticipated by the '575 patent.

For all the foregoing reasons, the asserted claims of the '446 patent are anticipated by the '575 patent.

IV. CONCLUSION

There are three independent reasons why summary judgment should be granted to defendants. There is no infringement because "PE" should not be construed to include UHMWPE. Therefore, FiberWire does not contain a yarn from the first set. The addition of coating to FiberWire leads to a finding of non-infringement because the undisputed evidence is that coating affects the basic and novel characteristics of the '446 patent. Finally, if the Court were to construe the term "PE" to include UHMWPE, the asserted claims of the '446 patent are invalid because the '575 patent discloses each limitation of those claims.

For all the foregoing reasons, summary judgment should be granted and DePuy Mitek's claims should be dismissed in their entirety.

Dated: August 11, 2006

Respectfully submitted,

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SUBSTITUTE EXHIBIT 10

Deposition of:
Dr. Matthew Hermes, Vol. I

June 27, 2006

Page 1

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

C.A. NO. 04-12457 PBS

COPY

-----x
DePUY-MITEK, INC.,

A Massachusetts Corporation,

Plaintiff,

vs.

ARTHREX, INC.,

A Delaware Corporation,

Defendants.
-----x

DEPOSITION OF DR. MATTHEW HERMES

Philadelphia, Pennsylvania

June 27, 2006

Reported by:

CONSTANCE S. KENT, CSR, RPR

JOB NO.: 350

1 invention during the time you were working at US
2 Surgical?

3 MR. BONELLA: Object to the form.

4 THE WITNESS: I don't recall.

5 BY MR. SABER:

6 Q. Would this definition of braid or
7 braided that you used in this patent result in yarns
8 that are in direct intertwining contact as you
9 understand that term from the '446 patent?

10 A. It's my opinion that the -- that the
11 sheath yarns would be in direct intertwining
12 contact.

13 Q. Now, in -- in your patent, this
14 definition of braid or braided didn't require that
15 there be a core, correct?

16 A. It did not require that there be a
17 core, that is correct.

18 Q. And the -- on column three, line ten,
19 it says the braided suture of this invention can
20 optionally possess in addition to the braided
21 structure itself a core component around which the
22 braid is constructed?

23 A. Yes.

24 Q. Is that correct?

25 A. That's correct, that's what it reads.

1 Q. Do you agree that Figure 6 is an
2 elongated member?

3 A. Yes, I do.

4 Q. And same thing about Figure 8?

5 A. Yes, I -- yes, sir.

6 Q. Okay. You would agree that this
7 patent discloses elongated members that are sutures,
8 correct?

9 A. I would agree that this patent
10 discloses elongated members, some of which are
11 described as sutures, yes.

12 Q. Let's go back to claim one, column
13 eight.

14 A. Yes, sir.

15 Q. Would you agree with me that the
16 first fiber includes ultra high molecular weight
17 polyethylene?

18 A. Claim one?

19 Q. Yes, sir.

20 A. Yes. It says ultra high molecular
21 weight, high tenacity is the material.

22 Q. And under this patent, that would
23 include ultra high molecular weight polyethylene?

24 A. If that's a question, I believe it
25 would, yes.

Deposition of:
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June 27, 2006

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1 Q. Okay. And now there's also -- the
2 ultra high molecular weight polyethylene in claim
3 one is braided with a second fiber, correct?

4 A. That is correct.

5 Q. And could you look to claim 11?

6 A. Yes.

7 Q. And does claim 11 -- would you agree
8 with me that claim 11 says that the second fiber
9 that's braided with the ultra high molecular weight
10 polyethylene is nylon?

11 A. Yes.

12 Q. Could you look at claim 12?

13 A. Yes.

14 Q. Would you agree with me that that
15 says that the second fiber braided with the ultra
16 high molecular weight polyethylene is polyester?

17 MR. BONELLA: Object to the form.

18 THE WITNESS: Yes.

19 BY MR. SABER:

20 Q. Is there -- in claim one, is there
21 any mention of a core?

22 A. No.

23 Q. In claim 11, is there any mention of
24 a core?

25 A. No.

1 together and there's no core, that that's one of the
2 things that falls within claim 11?

3 MR. BONELLA: Object to the form.

4 THE WITNESS: Yes.

5 BY MR. SABER:

6 Q. Okay. And same thing with respect to
7 claim 12?

8 A. Yes.

9 MR. BONELLA: Object to the form.

10 THE WITNESS: I'm sorry. Yes.

11 BY MR. SABER:

12 Q. The -- could you look back at Figure
13 6?

14 A. Yes.

15 Q. Are the -- the various yarns 26 that
16 are shown in Figure 6, are they in direct
17 intertwining contact with each other?

18 A. It's my opinion that -- yarns 26 as
19 described in --

20 MR. BONELLA: Object to the form of
21 the question.

22 MR. SABER: Let me rephrase it.

23 BY MR. SABER:

24 Q. Do you agree that the yarns 26 --
25 that are denoted as 26 in Figure 6?

6/27/2006 Hermes, Matthew

1 A. Yes.

2 Q. Right? That those yarns are in
3 direct intertwining contact as that term is used in
4 the '446 patent?

5 A. I believe they are, yes.

6 Q. Let me ask you about Figure 8. Do
7 you see the yarns denoted by the numbers 30?

8 A. Yes.

9 Q. Do you agree that the yarns denoted
10 by number 30, Figure 8, are in direct intertwining
11 contact with each other as that term is used in the
12 '446 patent?

13 A. I believe that they're in direct
14 intertwining contact with each other as sheath
15 yarns. The core yarn is not.

16 Q. Well, the 30s are all in the sheath,
17 correct?

18 A. Yes, sir.

19 Q. Right. And the 30s are not in the
20 core, correct?

21 A. Yes.

22 Q. I was asking about the 30s.

23 A. Yes, sir.

24 Q. Just so the record is clear, do you
25 agree that the yarns 30 from Figure 8 are in direct

Deposition of:
Dr. Matthew Hermes, Vol. I

June 27, 2006

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1 A. I do not have that understanding. I
2 understood your question and that is my answer.

3 Q. Okay. Assume with me that each one
4 of the yarns -- do you see in Figure 6 there are a
5 dozen or so yarns that are depicted?

6 A. Yes, sir.

7 Q. Assume with me that each one of those
8 is a 26.

9 A. We can do that.

10 Q. Okay.

11 A. Yes, sir.

12 Q. Would you agree with me that at least
13 one of those 26s is ultra high molecular weight
14 polyethylene?

15 A. Yes.

16 Q. And do you understand that more than
17 one can be ultra high molecular weight polyethylene?

18 A. Yes.

19 Q. And do you have an understanding that
20 one or more of the 26s can be a nonabsorbable yarn?

21 A. Yes.

22 Q. Let me turn to the Burgess
23 application, which is Exhibit 7 to your report, your
24 first report.

25 A. Yes, sir.

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Dr. Matthew Hermes, Vol. I

June 27, 2006

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1 question, if I may.

2 Am I correct that you don't provide
3 an example of a braided construction without direct
4 intertwining contact where there is no core in your
5 report?

6 MR. BONELLA: Object to form.

7 BY MR. SABER:

8 Q. Let me rephrase that again.

9 A. Yeah, try it again.

10 Q. In your report am I correct that you
11 provide no example of a braided construction where
12 there is no direct intertwining contact of a -- of a
13 construction that does not have a core?

14 A. See if this answers your question. I
15 do not believe in my report that I provide in a
16 noncore construction a braid without intertwining
17 contact.

18 Q. Without direct intertwining contact?

19 A. Without direct intertwining contact.

20 Is that --

21 Q. That answers my question.

22 A. Is that an answer to your question?

23 Q. Yes, sir, it is.

24 A. Okay.

25 Q. And as you sit here today, can you

Deposition of:
Dr. Matthew Hermes, Vol. I

June 27, 2006

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1 give me an example of a braided construction which
2 does not have direct intertwining contact where
3 there is no core?

4 A. I'd have to think about it. I don't
5 know the answer to that.

6 Q. Okay.

7 MR. SABER: Why don't we take a break
8 at this point?

9 THE VIDEOGRAPHER: Going off the
10 record.

11 The time on the video monitor is
12 4:04 PM.

13 (Recess.)

14 THE VIDEOGRAPHER: Going back on the
15 record. The time on the video monitor is 4:24 PM.

16 Please continue.

17 BY MR. SABER:

18 Q. Dr. Hermes, I'd like to ask you a
19 little bit about the Cohan article, if I'm
20 pronouncing that correctly, which I believe is
21 Exhibit 8 to your report.

22 A. Yes, sir.

23 Q. The -- would you -- would you agree
24 with me that the Cohan article discloses the use of
25 ultra high molecular weight PE in a suture

Deposition of:
Dr. Matthew Hermes, Vol. II

July 25, 2006

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1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS

4 _____ x

5 DePUY-MITEK, INC.,

6 A Massachusetts Corporation,

7 Plaintiff,

8 vs.

9 ARTHREX, INC.,

10 A Delaware Corporation,

11 Defendants.

12 _____ x

13 DAY 2 OF 2

14 CONTINUED VIDEOTAPED DEPOSITION

15 OF DR. MATTHEW HERMES

16 Philadelphia, Pennsylvania

17 July 25, 2006

18

19

20 Reported by:

21

22 PAMELA HARRISON, RMR, CRR, CSR

23

24

25

ORIGINAL

		Page 345
1	Q. -- the date -- the date of -- the	01:15:49p
2	filing date of the '446 patent?	01:15:50p
3	MR. BONELLA: That was a	01:15:52p
4	different question.	01:15:53p
5	MR. SABER: Let me rephrase it.	01:15:53p
6	BY MR. SABER:	01:15:55p
7	Q. Do you have any evidence that Ethicon	01:15:55p
8	sterilized a suture within the claims of the '446	01:15:58p
9	patent prior to the filing date of that patent?	01:16:02p
10	A. I have no such evidence.	01:16:06p
11	Q. Now, the February 2, 1989, sutures	01:16:12p
12	that you discuss in your report were not	01:16:16p
13	sterilized, isn't that correct?	01:16:18p
14	A. I don't know that. They're not	01:16:19p
15	described as sterilized, but I certainly don't	01:16:20p
16	know that for certain.	01:16:23p
17	Q. Did you review Dr. Steckel's testimony	01:16:24p
18	where he talked about whether those sutures were	01:16:31p
19	sterilized?	01:16:36p
20	A. If he talked about it, I don't	01:16:37p
21	remember what he said.	01:16:38p
22	Q. Let's see if we can --	01:16:39p
23	MR. SABER: Could you mark this	01:16:42p
24	as the next exhibit.	01:16:43p
25	(Whereupon a document was	01:16:47p

		Page 346
1	marked, for identification purposes, as	01:16:47p
2	Defendant's Exhibit-194.)	01:16:48p
3	MR. BONELLA: Thank you.	01:17:18p
4	BY MR. SABER:	01:17:18p
5	Q. Let me show you Dr. -- or at least the	01:17:18p
6	second volume of Dr. Steckel's deposition, and I	01:17:23p
7	just want to draw your attention to a couple of	01:17:27p
8	pages.	01:17:29p
9	This is -- we've shown you	01:17:31p
10	what's been marked as Defendant's Exhibit-194	01:17:32p
11	which is the second volume of Dr. Steckel's	01:17:35p
12	deposition.	01:17:40p
13	A. And that's what I have, Mr. Saber,	01:17:40p
14	thank you.	01:17:44p
15	Q. Yes, sir. And if you could look at	01:17:44p
16	Page 221 of that?	01:17:46p
17	A. Okay.	01:17:48p
18	Q. You see that there's a discussion of	01:17:49p
19	the February 2, 1989, entry from his lab	01:17:53p
20	notebook?	01:17:56p
21	A. (Witness reviewing document.)	01:18:20p
22	Where's the beef?	01:19:22p
23	Q. Page 221 of his deposition --	01:19:22p
24	A. Mm-hmm, okay.	01:19:24p
25	Q. -- is where that's discussed. Do you	01:19:25p

SUBSTITUTE EXHIBIT 19

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS
4

COPY

5 DePUY MITEK, INC.,)
6 Plaintiffs,)
7 vs.)
8 ARTHREX, INC., a Delaware)
9 corporation,)
Defendants.)

10
11
12 DEPOSITION of DR. MARK G. STECKEL,

13 called as a witness by and on behalf of the
14 Defendant, pursuant to the applicable provisions of
15 the Federal Rules of Civil Procedure, before P.
16 Jodi Ohnemus, Notary Public, Certified Shorthand
17 Reporter, Certified Realtime Reporter, and
18 Registered Merit Reporter, within and for the
19 Commonwealth of Massachusetts, at the Courtyard
20 Marriott, 423 Speen Street, Natick, Massachusetts,
21 on Thursday, 26 January, 2006, commencing at 10:44
22 a.m.
23
24
25

1 Q. Yes, one of the things. I didn't mean
2 that to be the only thing.

3 A. Okay. Well --

4 Q. That's fine.

5 A. Yeah.

6 MR. BONELLA: Object to form.

7 Q. I asked you if you needed a clarification
8 to do that.

9 A. Yeah.

10 Q. So, that's why.

11 A. Okay. So, yes, that was one of the things
12 that it could have contributed to.

13 Q. Anything else on handling properties?

14 MR. BONELLA: Object to form.

15 A. It's been a while since I've been in the
16 suture business, but I can't think of anything else
17 that it would have -- that it would relate to,
18 other than what we just described for handling.

19 Q. Is it -- how about how the knot is tied --
20 knot tie-down, or is knot tie-down part of the same
21 thing as chatter?

22 A. Knot tie-down is part of the same handling
23 properties. And the -- how tight the knot gets is
24 also related, and that's -- going back to the
25 question, if I could, on knot strength, the

1 Ethicon had multiple development programs going,
2 some of which were to make a product that were --
3 had better properties than silk, and silk has
4 really good handling properties. Some of them had
5 to do with higher strength sutures. Some of them
6 had to do with different biologic profiles in terms
7 of strength retention over time. And the initial
8 discussions were how can we address those types of
9 problems with a combination of fiber types.

10 So, the initial conversations -- and one
11 of the avenues that came out of that was this maybe
12 opportunity to have a suture that has strength
13 better than silk, but pliability like silk. So,
14 that was one of them.

15 Q. Okay.

16 A. And that was one that Al and Art had
17 considered in the past. Again, I'm not clear how
18 far they took that in the past, but they at least
19 considered that. And that was one that we elected
20 to pursue earlier than later, because we had the
21 materials, essentially. We thought it was good
22 opportunity.

23 Q. So, if I understand your testimony -- at
24 least at the very beginning stage you wanted
25 something that was stronger than silk but handled

1 as well as silk, is that --

2 A. That was certainly one of the embodiments
3 we were going after.

4 Q. As the -- as the project -- as the
5 project progressed and as you applied for a patent,
6 is it correct that you were trying to get something
7 that handled better than a homogenous braid but
8 didn't lose strength -- appreciably lose strength
9 from the conventional homogenous braid?

10 A. The overall project, yeah, I think that
11 was -- that would be a fair assessment of the
12 objective of the overall project.

13 Q. All right. And the conventional
14 homogenous braid that you were talking about that
15 you wanted to not lose appreciative strength then
16 was Ethibond, is that correct?

17 A. Right. Ethibond -- well, Ethibond, you
18 know, had good strength, but maybe not as good
19 handling properties as silk,.

20 Q. Right.

21 A. Silk had lower strength, good handle
22 properties, and again, one of the concepts was we
23 -- maybe we could get the best of both.

24 Q. All right. But as you applied for the 446
25 patent, was it the object there to have something

1 interest in how do you improve the knot strength of
2 them, and can you -- that was -- that was something
3 we discussed.

4 Q. I'm not sure I understand your answer.

5 A. Go ahead.

6 Q. And I'm trying to --

7 A. Sure.

8 Q. When you had this idea that you could
9 blend Dyneema together with PET, were you -- did
10 you believe it would make an acceptable suture or
11 an unacceptable suture?

12 A. No. We believed -- we believed that that
13 could offer a suture with straight tensile that was
14 better than Ethibond, and you know, could
15 potentially solve the knot issues, and again, that
16 was a generic view for all of the high-tenacity
17 fibers.

18 Q. You thought it was a good idea --

19 A. Yes. Yes.

20 Q. -- rather than a bad idea?

21 A. No, we viewed -- we viewed that as a
22 potential good idea.

23 Q. And you didn't think, Oh, that's a bad
24 idea.

25 MR. BONELLA: Objection. Asked and

Continued Deposition of:
Dr. Mark Steckel, Vol. II

February 3, 2006

Page 209

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS
4 DAY II

COPY

5 DePUY MITEK, INC.,)
6 Plaintiffs,)
7 vs.)
8 ARTHREX, INC., a Delaware)
9 corporation,)
Defendants.)

10
11
12 CONTINUED DEPOSITION of DR. MARK

13 G. STECKEL, called as a witness by and on behalf of
14 the Defendant, pursuant to the applicable
15 provisions of the Federal Rules of Civil Procedure,
16 before P. Jodi Ohnemus, Notary Public, Certified
17 Shorthand Reporter, Certified Realtime Reporter,
18 and Registered Merit Reporter, within and for the
19 Commonwealth of Massachusetts, at the Hilton Hotel,
20 25 Allied Drive, Dedham, Massachusetts, on Friday,
21 3 February, 2006, commencing at 9:06 a.m.

1 Q. Were the braids -- was a tipping put on
2 the braids?

3 A. There would not be tipping, since we never
4 intended to attach needles to this evaluation.

5 Q. Were the braids sterilized?

6 A. Typically at this level -- the answer is,
7 I believe, no. At this point in an evaluation, we
8 would typically evaluate presterile properties.

9 Q. Okay. Could you turn to Page 2638. So,
10 the fourth page of the --

11 A. Yes.

12 Q. -- fourth page of this -- the entry.
13 Under "Discussion," the first sentence says, "From
14 a braid processing viewpoint, the commingled yarn
15 was the least problematic braid, followed by the
16 yarn blend. The carrier blend presented the most
17 difficulties in core popping and braid looseness."

18 What did you mean by "The carrier blends
19 presented the most difficulties in core popping and
20 braid looseness"?

21 A. Core popping is a common braid defect.
22 You know, any braid text would -- would cover it.
23 The ability to adjust the tension on the yarn that
24 affects core popping was more difficult with the
25 carrier blend and the yarn blend than the

1 Q. Could you read her note for the record,
2 please.

3 A. Yes. "Being reviewed as potential new
4 product for Ethicon. May offer significant
5 advantages if technical problems of mixing of
6 materials with dissimilar stress/strain properties
7 can be overcome."

8 Q. Okay. Do you have an understanding of
9 what was meant by "-- if technical problems of
10 mixing of materials with dissimilar stress/strain
11 properties can be overcome"?

12 A. I believe she's referring to the tension
13 issues on processing the heterogeneous yarns.

14 Q. That we've discussed last week and earlier
15 today?

16 A. That would be my understanding.

17 Q. All right. And is it your understanding
18 that those --

19 A. Although this is Barbara's words, not
20 mine.

21 Q. That's what I'm trying to under -- to get
22 your understanding.

23 A. Yeah.

24 Q. And is it your understanding that those
25 technical problems with tension had not yet been

1 overcome as of February 8th, 1990?

2 MR. BONELLA: Object to the form.

3 A. I don't know if -- if Barbara at the
4 director level or manager level would have had
5 firsthand knowledge of that, so --

6 THE WITNESS: I'm sorry. Could you repeat
7 the question.

8 (Question read back.)

9 A. Once again, I think we're in the realm of
10 manufacturing requirements versus proof of concept
11 requirements in terms of have the technical
12 problems been overcome?

13 Q. Well, was it your understanding that --
14 well, do you understand -- do you know the basis of
15 Ms. Schwartz's comment, what that was based upon --
16 what her comment was based upon?

17 A. No, I'm inferring it from -- from the
18 comments and from what we've read.

19 Q. Okay. So, do you have an understanding
20 one way or another exactly what she was talking --
21 well, strike that.

22 MR. SABER: Why don't we take our break.

23 (Recess was taken.)

24 Q. Doctor Steckel, there came a time, of
25 course, when Ethicon applied for the 446 patent, of

1 A. To the amount of surface area in the
2 multifilament braid and the potential for -- let's
3 just leave it at that: The amount of surface area
4 between a multifilament versus a monofilament.

5 Q. Does it have to do with the roughness of
6 the braid versus smoothness of the braid?

7 A. Less to do with that, more to do with the
8 fact that the multifilament braid has interstices
9 (sp) that, you know, could potentially harbor
10 bacteria, etcetera.

11 Q. Going back to this paragraph that begins
12 at Line 26, it then goes on to speak about, "For
13 example, multifilament sutures almost universally
14 possess a surface coat to improve handling
15 properties." Is improving handling properties one
16 of the specific properties of multifilament braids
17 that is -- that coating -- that this paragraph is
18 saying coating is designed to improve?

19 MR. BONELLA: Object to form.

20 A. I'm sorry.

21 Q. Let me rephrase that. That was --

22 A. Yeah. I'm sorry.

23 Q. It says, "For example, multifilament
24 sutures almost universally possess a surface
25 coating to improve handling properties." Do you

1 **see that?**

2 A. Yes.

3 **Q. What's your understanding of what handling**
4 **properties are being referred to in that sentence?**

5 A. My understanding, because the surface
6 coating would be for knot handling, knot tie-down
7 handling properties.

8 **Q. Knot tie-down?**

9 A. Knot tie-down.

10 **Q. Anything else?**

11 A. Not to my understanding.

12 **Q. How about how well the knot slides, is**
13 **that one of the things that --**

14 A. Oh, yeah. That's part of knot tie-down.

15 **Q. Why don't you explain to me what is part**
16 **of knot tie-down.**

17 A. Okay. Yeah. I mean, knot tie-down refers
18 to the properties of a suture during the tying
19 process, which would include the force, smoothness,
20 roughness when one arm of the suture is being
21 pulled against the second arm of the suture.

22 **Q. How about is -- is coating designed to**
23 **help the -- the suture go through tissue more**
24 **easily?**

25 MR. BONELLA: Objection. Calls for expert

SUBSTITUTE EXHIBIT 28

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS

4 _____ x

5 DePUY-MITEK, INC.,
6 A Massachusetts Corporation,
7 Plaintiff,

8 vs.

9 ARTHREX, INC.,
10 A Delaware Corporation,
11 Defendants.

12 _____ x

13 CONFIDENTIAL - OUTSIDE COUNSELS' EYES ONLY

14 DAY 1 OF 2

15 DEPOSITION OF DR. DAVID S. BROOKSTEIN

16 Philadelphia, Pennsylvania

17 July 26, 2006

18

19

20 Reported by:

21

22 PAMELA HARRISON, RMR, CRR, CSR

23

24

25

ORIGINAL

	Page 54
1 of the question.	08:59:18a
2 THE WITNESS: I have no --	08:59:19a
3 BY MR. SABER:	08:59:20a
4 Q. Is it PET?	08:59:20a
5 A. PET and polyester are used	08:59:21a
6 interchangeably, yes. The polyethylene	08:59:23a
7 terephthlate is the official chemical name for	08:59:28a
8 polyester. Polyester is essentially a shorthand	08:59:32a
9 way of referring to polyethylene terephthlate.	08:59:36a
10 Q. Okay.	08:59:40a
11 A. Whenever you see those terms, they're	08:59:41a
12 the same thing.	08:59:42a
13 Q. Polyester, or...?	08:59:43a
14 A. Polyester and polyethylene	08:59:43a
15 terephthlate, T-E-R-E-P-T-H-L-A-T-E, and polyester	08:59:51a
16 are used interchangeably, in the literature, in	09:00:00a
17 the science, in teaching, by everybody.	09:00:03a
18 Q. Okay. And poly -- I have a little	09:00:09a
19 trouble with this --	09:00:12a
20 A. Okay.	09:00:15a
21 Q. -- polyethylene terephthlate --	09:00:15a
22 A. Terephthlate.	09:00:16a
23 Q. -- is referred to as PET?	09:00:16a
24 A. That is correct.	09:00:17a
25 Q. The -- could you -- I just want to tie	09:00:19a

	Page 165
1 about sutures, but actually designing and	11:16:23a
2 developing and the quality associated with that	11:16:25a
3 was for U.S. Surgical; I don't recall if we	11:16:32a
4 coated or not.	11:16:34a
5 Q. You just don't remember from that	11:16:35a
6 project?	11:16:38a
7 A. Right.	11:16:38a
8 Q. Do you recall whether you've had any	11:16:38a
9 experience with respect to coating of sutures in	11:16:40a
10 your background prior to your work on this case?	11:16:44a
11 A. I don't recall, because, you know, we	11:16:49a
12 looked at the vascular prosthesis patent that had	11:16:51a
13 sutures on it, I don't recall if they were coated	11:16:53a
14 or not. I don't know.	11:16:56a
15 Q. Have you -- do you recall whether you	11:16:58a
16 have had any experience with respect to what	11:17:01a
17 coating -- how coating impacts on suture	11:17:08a
18 properties?	11:17:11a
19 A. Well, I've looked at the Gitis report	11:17:15a
20 and tried to --	11:17:19a
21 Q. I'm sorry, prior to your work in this	11:17:20a
22 case.	11:17:21a
23 A. Not prior to the work in this case.	11:17:22a
24 Q. Okay. The -- would it be correct to	11:17:23a
25 say that what you've learned about coating and	11:17:31a

Page 166

1 its impact on suture properties is in conjunction 11:17:33a

2 with your work on this case? 11:17:35a

3 A. That would be proper to say that, yes. 11:17:38a

4 Q. The -- do you have an opinion as to 11:17:44a

5 whether it is generally well-known in the suture 11:17:45a

6 art that coating multifilament suture improves 11:17:48a

7 the tactile smoothless -- smoothness, pliability, 11:17:53a

8 and knot tie-down performance of that suture? 11:17:58a

9 A. That's a long question. Do that -- 11:18:02a

10 let's do that slower and -- 11:18:05a

11 Q. Sure, I'll even try to take it into 11:18:06a

12 parts. 11:18:09a

13 A. Yeah. 11:18:09a

14 Q. Do you have an opinion -- well, let me 11:18:09a

15 ask you this. Is it correct that it is generally 11:18:12a

16 known in the suture art that coating a 11:18:14a

17 multifilament suture improves the tactile 11:18:16a

18 smoothness of the suture? 11:18:18a

19 MR. BONELLA: Objection; incomplete 11:18:22a

20 hypothetical. 11:18:23a

21 THE WITNESS: I haven't seen 11:18:24a

22 anything that says that. 11:18:25a

23 BY MR. SABER: 11:18:26a

24 Q. You don't have an opinion one way or 11:18:26a

25 the other? 11:18:28a

		Page 167
1	A. I have no opinion on that.	11:18:28a
2	Q. Do you know whether it is generally	11:18:29a
3	known in the suture art that coating a	11:18:31a
4	multifilament suture improves the pliability of	11:18:35a
5	that suture?	11:18:39a
6	MR. BONELLA: Objection; incomplete	11:18:40a
7	hypothetical.	11:18:41a
8	THE WITNESS: Yeah, I've seen	11:18:42a
9	nothing like that. I can't judge that.	11:18:43a
10	BY MR. SABER:	11:18:45a
11	Q. You have no opinion one way or the	11:18:45a
12	other?	11:18:47a
13	A. I have an opinion that coating only	11:18:47a
14	affects in a minor way the handleability.	11:18:49a
15	Q. Okay.	11:18:52a
16	A. That's it.	11:18:52a
17	Q. Okay. Well, let me -- what do you	11:18:52a
18	mean when you say handleability?	11:18:55a
19	A. You know, if the guy does this	11:18:56a
20	(indicating) and says it feels smooth, then	11:18:58a
21	that's all. And even that from what I've read in	11:19:00a
22	some of your experts' reports, like Burks', even	11:19:06a
23	that is almost imperceptible.	11:19:09a
24	Q. Is it -- do you agree that it is	11:19:16a
25	generally known in the suture art that coating a	11:19:20a

	Page 168
1 multifilament suture improves the knot tie-down	11:19:22a
2 performance of that suture?	11:19:25a
3 MR. BONELLA: Objection; incomplete	11:19:27a
4 hypothetical.	11:19:29a
5 THE WITNESS: I've seen no	11:19:29a
6 evidence where that's discussed.	11:19:31a
7 BY MR. SABER:	11:19:33a
8 Q. So you don't have an opinion one way	11:19:33a
9 or the other?	11:19:37a
10 MR. BONELLA: Objection;	11:19:37a
11 incomplete --	11:19:38a
12 BY MR. SABER:	11:19:39a
13 Q. Is that correct?	11:19:39a
14 MR. BONELLA: Incomplete	11:19:40a
15 hypothetical on that previous question.	11:19:41a
16 THE WITNESS: My opinion is	11:19:43a
17 that coating only has an immaterial effect that	11:19:43a
18 might -- might -- affect handleability, and	11:19:47a
19 that's all.	11:19:51a
20 BY MR. SABER:	11:19:51a
21 Q. What is that opinion based on?	11:19:51a
22 A. It's based mostly on some of the work	11:19:53a
23 I've read from Gitis. It's an opinion of looking	11:19:55a
24 at the micrographs that I took and seeing the	11:19:59a
25 level of coating that was on those sutures. It's	11:20:02a

	Page 169
1 a -- it's based on some theoretical calculations	11:20:06a
2 I made associated with bending rigidity. It's	11:20:12a
3 understanding how tensile properties of fibers	11:20:17a
4 relate to the tensile properties of the braided	11:20:21a
5 structure. In no case can you show that coating	11:20:24a
6 does anything of any material. It's almost an	11:20:27a
7 afterthought to put it on.	11:20:31a
8 I think the patent even says, you	11:20:45a
9 know, in some cases it's expensive, don't even	11:20:46a
10 bother with it, it's not that a big deal. It's	11:20:51a
11 expensive and don't even put it on it.	11:20:54a
12 Q. Just give me a moment.	11:20:57a
13 A. I just want to read from the patent.	11:21:09a
14 MR. BONELLA: Why don't you wait	11:21:12a
15 until there's a question.	11:21:13a
16 THE WITNESS: Okay. Okay. Okay.	11:21:14a
17 MR. BONELLA: There's no question.	11:21:15a
18 (Whereupon a document was	11:21:32a
19 marked, for identification purposes, as	11:21:32a
20 Defendant's Exhibit-202.)	11:21:33a
21 THE VIDEOGRAPHER: Going off the	11:21:54a
22 video record.	11:21:55a
23 (A discussion was held off the	11:22:15a
24 record from 11:21 AM to 11:22 AM, with the video	11:22:15a
25 record then resuming.)	11:22:20a

	Page 211
1 from the second set, and the dissimilar yarns	12:02:23p
2 have at least some different properties that	12:02:28p
3 contribute to the overall properties of the	12:02:31p
4 braid. That is what I've been asked to assume.	12:02:31p
5 That is what my opinions are based on, those	12:02:33p
6 basic and novel characteristics.	12:02:36p
7 Q. In your opinion, sir, if the coating	12:02:38p
8 improves one of the properties that one of the	12:02:40p
9 materials contributes to the braid, can it have a	12:02:42p
10 -- can it materially affect the basic and novel	12:02:45p
11 characteristics of the invention?	12:02:48p
12 A. Not under this definition, no.	12:02:50p
13 Q. Your answer is no?	12:02:51p
14 A. The answer is no.	12:02:52p
15 Q. Okay.	12:02:55p
16 MR. SABER: Mike, this is	12:02:55p
17 probably a pretty good time.	12:02:56p
18 MR. BONELLA: Okay.	12:03:00p
19 BY MR. SABER:	12:03:00p
20 Q. What's the basis for that opinion?	12:03:00p
21 A. The basis for what opinion?	12:03:01p
22 Q. What you just said, that even if it	12:03:02p
23 improves the property that one of the yarns adds,	12:03:05p
24 it cannot affect the basic and novel	12:03:10p
25 characteristics.	12:03:12p

		Page 276
1	equivalents?	02:29:00p
2	A. Okay. Let me -- let me go through my	02:29:05p
3	report.	02:29:07p
4	First we look at each -- you make	02:29:07p
5	a table and we look at each claim or claim	02:29:10p
6	element and we see what that claim element or	02:29:13p
7	claim is claiming.	02:29:17p
8	Then we look under the function	02:29:18p
9	of the claim limitation. Okay? We see what it	02:29:21p
10	-- what is it -- what is the function of this, we	02:29:25p
11	make a determination what the function is, and	02:29:26p
12	then we compare it to what the function is of the	02:29:28p
13	material that's in question and we match the	02:29:31p
14	functions. Okay?	02:29:33p
15	Then we see -- once we've	02:29:34p
16	determined what the function is, we see the way	02:29:37p
17	that it met that function. And after that, we	02:29:40p
18	see what the final results are.	02:29:43p
19	So we're always -- we take the	02:29:43p
20	claim. Okay? We decide what the function,	02:29:45p
21	way or result is that we're trying to achieve,	02:29:49p
22	and then we look at the material in question	02:29:51p
23	and see if it meets the function, way and	02:29:53p
24	result for it to be an insubstantial	02:29:56p
25	difference.	02:29:58p

	Page 279
1 yarn from the second set.	02:33:10p
2 A. Right.	02:33:13p
3 Q. Correct?	02:33:13p
4 A. Right.	02:33:14p
5 Q. Now, was that your opinion or was that	02:33:14p
6 the function -- was that function given to you by	02:33:16p
7 the attorneys?	02:33:19p
8 A. No, it was the function that I got	02:33:19p
9 from the '446 patent. It says, My opinion	02:33:21p
10 regarding the function of the first fiber	02:33:25p
11 material is supported by the '446.	02:33:27p
12 Q. No --	02:33:29p
13 A. Let me --	02:33:30p
14 Q. I just want you to answer my	02:33:31p
15 question. I mean, was this -- I'm just trying to	02:33:33p
16 find out does this -- are you the one who came up	02:33:36p
17 with the function, or was that something that was	02:33:39p
18 an assumption that was given to you by the	02:33:40p
19 attorneys?	02:33:43p
20 MR. BONELLA: Objection. Asked	02:33:43p
21 and answered.	02:33:44p
22 BY MR. SABER:	02:33:44p
23 Q. That's my question.	02:33:44p
24 A. Mr. Falke explained to me how the	02:33:47p
25 function/way result works from a legal	02:33:50p

	Page 284
1 test that you set forth for function?	02:38:36p
2 A. Can you repeat that, or can you read	02:38:42p
3 it back?	02:38:44p
4 Q. Let me rephrase it.	02:38:46p
5 Am I correct that any yarn would	02:38:48p
6 meet the function test, as you set forth, as long	02:38:54p
7 as it contributed a property to the suture	02:38:58p
8 different from the property contributed by the	02:39:01p
9 yarn of the second set?	02:39:03p
10 A. That is what I wrote, yes.	02:39:05p
11 Q. In coming up with the function, did	02:39:13p
12 you consider the function set forth -- the	02:39:18p
13 function set forth in the patent for the specific	02:39:23p
14 yarns identified in the first set of yarns?	02:39:27p
15 A. Yes, I say that. If we go to the --	02:39:32p
16 if we go to the patent and I'll show you where	02:39:35p
17 that is. It's right here (indicating), under Tab	02:39:37p
18 D, Column 2, Lines 50 to 52, and Column 3, Lines	02:39:41p
19 43 to 48. I think that's in the -- I cited the	02:39:51p
20 patent there.	02:39:56p
21 Do you want to go to the patent	02:39:57p
22 and we can talk about it?	02:39:58p
23 Q. Sure. Let's start with -- I do want	02:39:59p
24 to ask you a couple of questions about that.	02:40:03p
25 A. Okay.	02:40:06p

		Page 285
1	Q. The first thing you say is Column 2,	02:40:06p
2	Lines 50 to 52, in the patent?	02:40:08p
3	A. Yes.	02:40:11p
4	Q. And this is Exhibit D?	02:40:11p
5	A. Yes, sir.	02:40:14p
6	Q. And that's the sentence that begins,	02:40:14p
7	Surprisingly --	02:40:16p
8	A. Yes.	02:40:17p
9	Q. -- the heterogeneous braids may	02:40:17p
10	exhibit -- well, tell me specifically what in	02:40:19p
11	that, because I know the numbers get a little bit	02:40:22p
12	off, as we know.	02:40:24p
13	A. I understand.	02:40:25p
14	Q. Tell me specifically what you're	02:40:26p
15	referring to at Column 2, Lines 50 to 52.	02:40:27p
16	A. Well, I also have it in my -- in my	02:40:31p
17	report, the -- I quoted, The patent explains that	02:40:35p
18	the first fiber-forming material is dissimilar to	02:40:38p
19	the second set -- second fiber, and the braid of	02:40:41p
20	the similar yarns provides, quote, from the	02:40:46p
21	patent outstanding properties attributable to the	02:40:49p
22	specific properties of the dissimilar	02:40:52p
23	fiber-forming materials which make up the braided	02:40:55p
24	yarns.	02:40:57p
25	Q. Yeah, I want -- I just want to know	02:41:00p

	Page 288
1 at the time I must have had that, the 3-43 to	02:43:13p
2 3-48.	02:43:17p
3 Q. Okay. Column 3, Lines --	02:43:17p
4 A. Column 3, Line 43 to 48.	02:43:20p
5 Q. Just so the record is clear, you're	02:43:23p
6 talking about Column 3, Lines 43 to 48?	02:43:24p
7 A. That is correct.	02:43:28p
8 Q. Is there anything in Column 3, Lines	02:43:28p
9 43 to 48, which is discussing the specific	02:43:30p
10 materials which you have from group A?	02:43:33p
11 A. Not that I can see.	02:43:52p
12 Q. Now, in coming to your opinion on the	02:43:53p
13 function --	02:43:56p
14 A. Yes.	02:43:57p
15 Q. -- for purposes of the doctrine of	02:43:57p
16 equivalents --	02:43:59p
17 A. Right.	02:44:00p
18 Q. -- did you consider the prosecution	02:44:00p
19 history of the '446 patent?	02:44:02p
20 A. Not -- not in any meaningful way, no.	02:44:05p
21 Q. What do you mean when you say	02:44:08p
22 meaningful?	02:44:09p
23 A. I didn't -- the answer is no.	02:44:10p
24 Q. Did you -- okay.	02:44:12p
25 A. I had access to the document, but I	02:44:13p

	Page 289
1 never looked at it.	02:44:16p
2 Q. Okay. Did you -- do you have any	02:44:16p
3 understanding of what the claims of the '446	02:44:19p
4 patent were as the patent application was	02:44:21p
5 originally filed?	02:44:26p
6 A. No.	02:44:27p
7 Q. Have you studied as to whether there	02:44:28p
8 were any amendments to the claims --	02:44:31p
9 A. No.	02:44:33p
10 Q. -- in the prosecution history?	02:44:33p
11 A. No.	02:44:35p
12 Q. Okay. Do you think that understanding	02:44:35p
13 the prosecution history in any amendments to the	02:44:39p
14 claims is important for understanding the	02:44:43p
15 function of limitation A?	02:44:46p
16 A. Not in an infringement situation, no.	02:44:53p
17 Q. Okay. You would agree with me that	02:44:59p
18 limitation A that we're discussing requires that	02:45:06p
19 the material be one of the specified listed	02:45:12p
20 materials to literally meet that limitation,	02:45:16p
21 correct?	02:45:20p
22 A. To literally meet it?	02:45:20p
23 Q. Yes.	02:45:22p
24 A. Yes.	02:45:22p
25 Q. Okay. Now, let me refer your	02:45:27p

	Page 290
1 attention to Paragraph 56 of your report.	02:45:55p
2 MR. BONELLA: The first report.	02:46:00p
3 MR. SABER: Yes, we're in the	02:46:01p
4 first report.	02:46:02p
5 BY MR. SABER:	02:46:02p
6 Q. On Page 21.	02:46:02p
7 A. Okay.	02:46:03p
8 Q. And you refer to the testimony of	02:46:04p
9 Mr. Hallet in that paragraph?	02:46:11p
10 A. Yes. Excuse me. Yes.	02:46:13p
11 Q. I'm sorry.	02:46:15p
12 A. Sorry.	02:46:16p
13 Q. And you refer to the testimony of	02:46:17p
14 Mr. Hallet that in the development of FiberWire	02:46:21p
15 he had constructed a 100 percent homogeneous	02:46:25p
16 ultra high molecular weight PE braid but Arthrex	02:46:29p
17 had requested a less stiff braid?	02:46:32p
18 A. That's what I write, yes.	02:46:36p
19 Q. Okay. Why did you rely upon that	02:46:39p
20 testimony? Or let me just and then the next	02:46:40p
21 sentence is, Mr. Hallet then made a heterogeneous	02:46:45p
22 braid of ultra high molecular weight polyethylene	02:46:48p
23 and PET to get the strength of ultra high	02:46:50p
24 molecular weight PET and the flexibility of PET?	02:46:53p
25 A. Yes.	02:46:57p

		Page 300
1	A. PET has a lower tensile modulus and	02:56:30p
2	can affect the tensile stiffness -- I mean, the	02:56:33p
3	bending stiffness in a positive fashion.	02:56:36p
4	Q. Do you mean make it easier to bend?	02:56:39p
5	A. Easier to bend.	02:56:41p
6	Q. Right. And --	02:56:42p
7	A. And easier to hold a knot.	02:56:43p
8	Q. Am I correct that adding the PET to	02:56:46p
9	the ultra high molecular weight braid made the	02:56:51p
10	braid easier to bend?	02:56:55p
11	A. That's what people have said, yes.	02:56:58p
12	Q. Do you believe that to be true?	02:57:00p
13	A. I believe that because it has a lower	02:57:03p
14	tensile modulus, it could make it easier to bend,	02:57:07p
15	that's correct. Modulus, M-O-D-U-L-U-S.	02:57:12p
16	Q. Would you expect that adding the PET	02:57:15p
17	would make the braid easier to bend?	02:57:21p
18	A. Adding or substituting?	02:57:23p
19	Q. Adding -- well, going from an all	02:57:24p
20	ultra high molecular weight PE braid --	02:57:30p
21	A. Right.	02:57:33p
22	Q. -- to a heterogeneous braid of the	02:57:34p
23	combination of ultra high molecular weight PE and	02:57:37p
24	PET would make the braid easier to bend; is that	02:57:40p
25	what your expectation is?	02:57:45p

		Page 301
1	A. In the context of this invention or in	02:57:46p
2	general?	02:57:49p
3	Q. In the context of this invention.	02:57:49p
4	A. In the context of this invention, yes.	02:57:51p
5	Q. Okay. In the context of this	02:57:54p
6	invention, is it your opinion that the ultra high	02:57:55p
7	molecular weight PE braid alone was not easy to	02:58:00p
8	bend?	02:58:05p
9	A. That it was -- it was -- I'm going by	02:58:06p
10	what Mr. Hallet testified, he said Arthrex	02:58:12p
11	requested a less stiff braid, so he went to a	02:58:14p
12	combination, a tailored combination, yes.	02:58:16p
13	Q. So that and would that be your	02:58:18p
14	expectation?	02:58:20p
15	A. That's what I would do.	02:58:20p
16	Q. In the context of this invention?	02:58:21p
17	A. In the context of this invention.	02:58:23p
18	Q. You would expect that the ultra high	02:58:24p
19	molecular weight braid would be -- would not be	02:58:26p
20	easy to bend?	02:58:29p
21	A. Right.	02:58:30p
22	Q. Okay.	02:58:31p
23	A. And he solved the problem by going to	02:58:31p
24	what's the novel and basic characteristics of our	02:58:36p
25	invention. The '446, it's not mine.	02:58:43p

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS

4 _____ x

5 DePUY-MITEK, INC.,
6 A Massachusetts Corporation,
7 Plaintiff,

8 vs.

ORIGINAL

9 ARTHREX, INC.,
10 A Delaware Corporation,
11 Defendants.

12 _____ x

13

14 DAY 2 OF 2

15 DEPOSITION OF DR. DAVID S. BROOKSTEIN

16 Philadelphia, Pennsylvania

17 July 27, 2006

18

19

20 Reported by:

21

22 PAMELA HARRISON, RMR, CRR, CSR

23

24

25

Page 399

1 A. It is my opinion that if the coating
2 in some miraculous way made those materials not
3 yarns anymore and they were no -- they were not
4 dissimilar anymore, that that would be a change.
5 If all of a sudden what was once a set of two
6 dissimilar yarns miraculously became, for
7 instance, a monofilament, that would be a change,
8 yeah.

10:24:09a

10:24:11a

10:24:15a

10:24:17a

10:24:22a

10:24:26a

10:24:29a

10:24:31a

9 Q. And that would affect the basic and
10 novel characteristics?

10:24:32a

10:24:33a

11 A. If the basic and novel characteristics
12 are two dissimilar yarns, yes, and all of a
13 sudden there weren't yarns in there anymore, it
14 was some new material that was -- that we don't
15 know about.

10:24:34a

10:24:35a

10:24:38a

10:24:41a

10:24:43a

16 Q. Or the yarns were the same yarns, made
17 the yarns into the same yarns?

10:24:44a

10:24:46a

18 A. If they were not dissimilar, right.

10:24:48a

19 Q. Right. So is it your opinion that if
20 the coating does not -- does not achieve the goal
21 that you just described, then it does not affect
22 the basic and novel characteristics of the
23 invention as Dr. Mukherjee defines it?

10:24:49a

10:24:54a

10:25:00a

10:25:02a

10:25:05a

24 A. Can you repeat the question.

10:25:07a

25 Q. Yeah, let me try and rephrase it.

10:25:08a

1	Is it your opinion that the	10:25:12a
2	coating -- if the coating does not transform	10:25:15a
3	the braided material into another structure,	10:25:20a
4	would you -- let me ask it this way. What do	10:25:24a
5	you mean when you say transform the braided	10:25:27a
6	FiberWire materials into another structure?	10:25:30a
7	A. What do I mean?	10:25:32a
8	Q. Yes.	10:25:33a
9	A. I mean it's not dissimilar yarns	10:25:34a
10	anymore, that would be an example of what I	10:25:36a
11	mean. That all of a sudden you had a set from A,	10:25:38a
12	a set from B and now it was some magical	10:25:41a
13	structure that wasn't yarns, it wasn't two sets,	10:25:45a
14	they were all the same, that would be a	10:25:48a
15	transformation.	10:25:50a
16	Q. Okay.	10:25:52a
17	A. It would be alchemy, but it would be a	10:25:52a
18	transformation.	10:25:56a
19	Q. Okay. If that transformation doesn't	10:25:56a
20	occur by the coating, then is it your opinion	10:25:58a
21	that the coating doesn't affect the basic and	10:26:01a
22	novel characteristics of the invention?	10:26:02a
23	MR. BONELLA: Objection.	10:26:04a
24	THE WITNESS: That's not what I	10:26:04a
25	said.	10:26:05a

3. Defendant Pearsalls, a United Kingdom company, is a braid manufacturer which makes the braids that eventually become FiberWire suture.

4. Ethicon, a Johnson & Johnson company, is related to DePuy Mitek and the original owner of the '446 patent. Ex. 18.

5. In 2001, Arthrex introduced a new suture, called FiberWire, for the orthopedic surgery market. Ex. 1 at 31:2-5.

6. FiberWire was so new and revolutionary that it spawned a new category of suture called "high-strength" suture. Ex. 2 at 2; Ex. 4 at 146:7-14.

7. FiberWire suture was the first "high-strength" suture introduced into the market. Ex. 2 at 2; Ex. 4 at 146:7-14.

8. FiberWire was more than twice as strong as the sutures conventionally used in orthopedic surgery, including Ethibond, the leading suture for the orthopedic market sold by Ethicon. Ex. 2 at 8.

9. FiberWire obtains its strength because it contains ultra high molecular weight polyethylene ("UHMWPE"), one of the strongest synthetic materials ever created.. Ex. 3 at § 1.

10. After seeing the impact of FiberWire, DePuy Mitek realized that without the introduction of its own high strength suture, it would not be able to meet its sales targets. Ex. 5.

11. DePuy Mitek's original idea was to introduce a "me too" suture that mimicked FiberWire. Ex. 5. In late 2004, DePuy Mitek introduced its own high strength suture called Orthocord, which also includes UHMWPE. Ex. 6.

12. Shortly before filing this lawsuit, the '446 patent was assigned from Ethicon to DePuy Mitek. Ex. 7. In this lawsuit, DePuy Mitek alleges that defendants infringe claims 1, 2, 8, 9 and 12 of the '446 patent ("the asserted claims").

13. Neither Ethicon, nor DePuy Mitek has never made a commercial product covered by the '446 patent. The '446 patent is a paper patent. Ex. 9.

14. Ethicon began the work that led to the '446 patent in 1988. As explained by inventor Steckel, this work was part of a larger project designed to examine possible suture improvements. Ex. 19 at 103:23-104:17.

15. At the time, a standard braided suture was Ethibond, a suture made entirely of PET polyester, which was braided to form the suture. Ex. 4 at 135:4-7.

16. Dr. Steckel's idea was to braid together two different substances, one to maintain as much of the strength of the suture as possible and the other to enhance the pliability (that is, bendability) and handleability of the suture. As Dr. Steckel explained, the goal was to produce a suture which maintained the strength of Ethibond (made of PET), while having the feel and pliability of silk, a substance known to be very pliable and easy to use. Ex. 19 at 103:23-104:17.

17. Ethicon built and test heterogeneous braids, made of PTFE and PET, by February 2, 1989. None of these braids, however, were sterilized. Ex. 19 at 225:5-8.

18. Ethicon never built a sterilized surgical suture that included all the limitations of the asserted claims before the filing date of the '446 patent. Ex. 10 at 345:7-10.

19. During his development work, Dr. Steckel observed that the prototype composite braid "ranked better than the silk and Ethibond in knot tie-down even without a coating." Ex. 21 at DMI 2666.

20. Dr. Steckel knew during the development work that lead to the '446 patent that UHMWPE had great strength. Ex.5 (to *Markman* Brief) at 190:12-191:3.

21. Ethicon filed the application that led to the '446 patent on February 19, 1992, three years after Dr. Steckel tested the braids. Ex. 8 at cover page.

22. The specification of the '446 patent begins with a summary of prior suture development, explaining that multi-filament braided sutures were developed to improve suture pliability compared to monofilament, unbraided sutures. Ex. 8 at col. 1, ll. 5-25.

23. The specification cautioned that mechanisms, such as coating, will adversely affect braid mobility and explained that "the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid." Ex. 8 at col. 1, ll. 26-29.

24. The first example presented in the specification is coating, which "improve[s] handling properties," but at the expense of braid pliability. Ex. 8 at col. 1, ll. 29-31.

25. The specification suggests that while a braid made entirely of "highly lubricious polymers" can be used to make a highly pliable braid, such a braid "will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments." Ex. 8 at col. 2, ll. 22-28.

26. This theme that lubricious polymers are too weak for suture usage is repeated when the specification explains that a "volume fraction of lubricating yarns . . . above 80% may adversely affect the overall strength of the braid." Ex. 8 at col. 4, ll. 50-54.

27. The specification then explains that the proposed solution is to have a suture comprised of a heterogeneous braid made of two different fiber forming materials which exhibits "improved pliability and handling properties . . . without appreciably sacrificing" [the suture's] physical properties," (Ex. 8 at col. 2, lines 31-37), namely its "physical strength and knot security." Ex. 8 at col. 2, l. 66. This proposed solution is repeated throughout the specification. Ex. 8 at col. 2, ll. 62-66; col. 6, ll. 7-8.

28. The '446 patent specifically refers to "pliability" in connection with "resistance to bending," (Ex. 8 at col. 1, ll. 11-15, 24) and "bending rigidity," (Ex. 8 at col. 6, ll. 44-45, col. 8 at Table, ll. 44-46), which are the inverse of pliability.

29. A handling property specifically identified in the '446 patent is "knot tie down." Ex. 8 at col. 6, ll. 7-8.

30. The '446 patent relies on what is called the "rule of mixtures" to attempt to demonstrate that this combination is an improvement in the art. The point made by the inventors is that gains in pliability and handleability by using the combination of highly pliable and lubricious, but relatively weak, materials with a stronger material outweighs the loss of suture strength. Ex. 8 at col. 8, ll. 22, 35 and 38.

31. The specification also discusses the use of coating on sutures. It explains that coating, if desired, can be added "to further improve the handleability and knot tiedown performance of the braid." The specification also states that it is better if coating is not used, explaining that if the braid "possesses a significant [amount] of the lubricious yarns, the conventional coating may be eliminated saving expense as well as the associated braid stiffening." Ex. 8 at col. 6, ll. 5-17.

32. Seven polymers (PTFE, FEP, PFA, PVDF, PETFE, PP and PE) are identified as the yarns that are included for lubricity so as to improve the overall pliability of the braid. Ex. 8 at col. 4, ll. 11-27.

33. Three materials, PET, nylon and aramid, are identified as the ones that could be used for improving the strength of the braid. Ex. 8 at col. 4, ll. 35-40. The term PE is never associated with the "strength" yarns.

34. Claim 1 of the '446 patent is to a surgical suture "consisting essentially of" a heterogeneous braid of a first and second set of yarns in a sterilized and braided construction. Ex. 8 at claim 1.

35. The remainder of the asserted claims ultimately depend from claim 1. Ex. 8 at claims 2, 8, 9, 12.

36. Claim 1 defines the first set of yarns as one of PTFE, FEP, PFA, PVDF, PETFE, PP and PE – the same materials identified in the specification as being pliable and lubricious. The claim defines the second set of yarns as one of PET, nylon and aramid – the same materials identified in the specification as being added for improving the strength of the braid. Ex. 8 at claim 1.

37. As the application for the '446 patent was originally filed, there were two sets of claims – one set for heterogeneous braids and a second set for surgical sutures made from heterogeneous braids. Ex. 22.

38. Ethicon was required to elect which set of claims it wanted to prosecute. The election was required because the patent examiner observed that they were distinct sets of claims where one set – the heterogeneous braid claims – were an intermediate product that could be used to make surgical sutures (the second set of claims) as well as other products. Ethicon elected to pursue the surgical suture claims. Ex. 23.

39. As originally filed, the first suture claim required only that the sterilized suture be comprised of two dissimilar yarns in direct intertwining contact. The specific materials were not part of the claim and it did not include the "consisting essentially of" limitation. Ex. 22.

40. In the first Office Action, the examiner rejected the suture claims based on U.K. patent application no. 2,218312A to Burgess ("the Burgess application") (Ex. 8 to *Markman* Brief).

41. The Burgess application disclosed a fishing line made of a heterogeneous braid where the braid was made of UHMWPE and either nylon or polyester. Ex. 8 (to *Markman* Brief). The examiner rejected the suture claims, explaining that the requirements for fishing line were similar to those of suture. Ex. 23 at 4.

42. In distinguishing the '446 patent from the Burgess application, Ethicon responded that because of its braided construction, "the fishing line of Burgess would have poor knot strength properties." [Emphasis in original.] Ethicon explained that the Burgess braid combination would have poor knot strength properties because it included UHMWPE. Ethicon stated that UHMWPE "gives the line minimal stretchability." [Emphasis in original.] Ex. 24 at 2.

43. Ethicon further explained that "although this thread has great strength properties, it suffers from low elongation and, in turn, poor knot strength properties." [Emphasis in original.] Ethicon concluded that, as a result of the different requirements of fishing line and suture, one should not look to the fishing line art. Ethicon also told the Patent Office that "[e]ven if one were to look to the fishing line art [the UHMWPE/polyester or nylon combination – the fishing line are presented by the Burgess application], one would inevitably design an unacceptable suture." Ex. 24 at 3-4.

44. Later during prosecution, Ethicon made two amendments to the claims. First, it abandoned the broad claims that required only that that braid be made of two dissimilar materials. Ex. 25 at 1. The allowed claims were limited to so that the dissimilar materials had to be from the group of specifically-named materials. Ex. 25.

45. The first set of yarns are from a group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE. The second set of yarns were from the group consisting of PET, nylon and aramid. Ex. 25.

46. The preamble of the claims was also amended to change the term “comprising” to “consisting essentially of.” Ex. 25 at 1.

47. UHMWPE is a stiff material. It is not a pliable material. Ex. 11 at ¶ 56; Ex. 10 at 306:20-307:4.

48. General purpose PE has been used in sutures and other materials for decades and is established as a general purpose commodity polymer. Ex. 3 at § 1.

49. UHMWPE was introduced as in fiber form in 1985 and is considered a specialized high performance product. Ex. 3 at § 1.

50. General purpose polyethylene and UHMWPE are not substitutes for each other. Ex. 12 (to *Markman* Brief) at 22.

51. The key structural characteristics of UHMWPE and general purpose polyethylene, molecular weight and molecular structure very different. Ex. 3 at § 2.

52. UHMWPE has a molecular weight in the range of 1 to 5 million, whereas general purpose PE has a molecular weight in the range of 50,000 to several hundred thousand. Ex. 3 at § 2.

53. UHMWPE exhibits a much higher degree of crystalline orientation and crystalline content as compared with general purpose polyethylene. Ex. 3 at § 2.

54. DePuy Mitek’s expert, Dr. Hermes’ first impression when reading the ‘446 patent was that it “seem[ed] to teach away from UHMWPE.” Ex. 14 (to *Markman* Brief); Ex. 10 at 336:23-23.

55. Based on the teachings of the ‘446 patent, Ethicon’s statements in the prosecution history and the differences between general purpose polyethylene and UHMWPE, the term “PE” in the asserted claims of the ‘446 patent means general purpose polyethylene and does not include UHMWPE. Accordingly, FiberWire does not contain a material from the first set of

yarns and does not infringe the asserted claims of the '446 patent literally or by the doctrine of equivalents.

56. The specification of the '446 patent identifies the basic and novel characteristics of the claimed invention as being a suture having two dissimilar yarns (of the materials claimed) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. This concept is repeated throughout the specification and is confirmed by the attorney who prosecuted the application for Ethicon and is consistent with Dr. Steckel's description of his work. Ex. 8 at col. 2, ll. 29 – 37; ll. 62 – 66; col. 4, ll. 11-40; col. 6, ll. 7 – 8; Ex. 8 at 110:14-20; Ex. 8 at 103:23—104:17.

57. Multiple patents, including patents owned by Ethicon and its expert, and publications (including from Ethicon) indicate that coating affects handleability characteristics of a suture, including knot tie-down. This was also asserted by Ethicon and DePuy Mitek when they developed suture products and was confirmed by several Ethicon and DePuy Mitek witnesses. Ex. 34, col. 1, ll. 14-18; Ex. 35, col. 1, ll. 11-15; Ex. 36, col. 1, ll. 12-15; Ex. 37, col. 1, ll. 19-25; Ex. 29 at 11; Ex. 28 at 525; Ex. 39; Ex. 40; Ex. 4 at 64:12-24; Ex. 41 at 48:11-49:2; Ex. 31 at 167:1-13; Ex. 18 at 295:23-296:7; Ex. 42 at 63:10-23; Ex. 14; Ex. 8 at col. 1, ll. 29-31; col. 6, ll. 5-8. As stated above, the '446 patent also states that coating improves the handling characteristics of the suture, including knot tie-down.

58. FiberWire contains a coating to improve handling characteristics, including suture slide, knot tying and ease of passing suture through tissue. Ex. 14.

59. For the reasons stated above, coating affect the basic and novel characteristics of the asserted claims of the '446 patent and its inclusion in FiberWire precludes infringement of those claims.

NOTE; THE REMAINING FACTS ARE SUBMITTED ONLY IF THE COURT CONSTRUES “PE” TO INCLUDE UHMWPE.

60. United States Patent No. 5,318,575 (“the ‘575 patent”) is prior art to the ‘446 patent. Ex. 15 at cover page; Ex. 8 at cover page.

61. Ethicon did not reduce to practice any product that included all the limitations of the asserted claims of the ‘446 patent before the filing date of the ‘446 because it never built a braid that was sterilized before the filing date, as shown above. “Sterilized” is a limitation of each asserted claim of the ‘446 patent. Ex. 8 at claim 1, 2, 8, 9, 12.

62. The ‘575 patent discloses every limitation of the asserted claims of the ‘446 patent. The ‘575 patent discloses a surgical suture. Ex. 15 at col. 2, l. 62; col. 3, ll. 2, 8, 15; col. 7, l. 26, 38, 43, 59; Ex. 10 at 212:25-213:5.

63. The ‘575 patent discloses a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set. Ex. 15 at col. 2, l. 65 – col. 3, l. 2; Ex. 10 at 170:6-12; Ex. 15 at claim 1.

64. FIG. 6 of the ‘575 patent discloses a spiroid braid with several yarns (items 26) that are braided in “direct intertwining contact.” Ex. 10 at 201:24-202:5.

65. The ‘575 patent discloses that one of the yarns braided together to form a suture is UHMWPE. Ex. 15 at col. 2, l. 31; Ex. 10 at 197:12-25

66. The ‘575 patent discloses that one of the yarns braided together to form a suture is PET or nylon. Ex. 15 at claim 11; claim 12; Ex. 10 at 198:7-11, 14-18.

67. The ‘575 patent discloses that the suture is attached to a needle. Ex. 15 at col. 5, ll. 41-42.

68. The '575 patent discloses that UHMWPE can be constitute a volume fraction in the braided sheath and core from about 20-80%. Ex. 15 at col. 4, ll. 8-24; Fig.6.

69. For these reasons, the '575 patent renders the asserted claims of the '446 patent invalid for anticipation.

Dated: August 11, 2006

Respectfully submitted,

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

_____)	
DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation)	
)	
Defendant.)	
_____)	

SUBSTITUTE DEFENDANTS ARTHREX, INC.'S AND PEARSALLS, LTD.'S
OPENING BRIEF ON CLAIM CONSTRUCTION

Dated: August 11, 2006

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I. INTRODUCTION

This is a patent infringement action involving U.S. Patent No. 5,314,446 (“the ‘446 patent”). Plaintiff DePuy Mitek, Inc. (“DePuy Mitek”) is alleging that defendants Arthrex, Inc. (“Arthrex”) and Pearsalls, Limited (“Pearsalls”) (together, “defendants”) infringe various claims of the ‘446 patent¹ by their respective activities in connection with FiberWire® surgical suture.

In *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996), the Supreme Court held that the meaning of patent terms is a matter of law for the Court to decide. Accordingly, pursuant to *Markman* and to the Court’s Order, dated June 19, 2006, entered in this case, defendants submit this opening brief on claim construction explaining their position as to the interpretation of the claim terms at issue in this litigation.

II. STATEMENT OF FACTS

Arthrex’s accused FiberWire® suture is the first high-strength suture to be introduced in the marketplace. Ex. 1 at 146:7-14. In fact, when it was first introduced in 2001, FiberWire was more than twice as strong as the conventional sutures on the market. Ex. 2 at 8. FiberWire attributes its high-strength to ultra high molecular weight polyethylene (“UHMWPE”), one of the strongest synthetic materials that has ever been created. Ex. 3 at § 1. The UHMWPE is braided together with a polyester known as PET.

The ‘446 patent, to the contrary, does not mention a high-strength suture as being one of the goals of the invention. Rather, the ‘446 patent recognizes that some suture strength will be sacrificed. Ex. 4 at col. 2, ll. 31-37; col. 2, l. 66. The ‘446 patent specification recognizes that there is a tradeoff between suture strength on the one hand and pliability on the other. Ex. 4 at col. 2, ll. 22-28. The ‘446 patent opts to concentrate on pliability and handleability improvement, stating that the goal is to improve pliability and handleability without appreciably

¹ The asserted claims of the ‘446 patent are claims 1, 2, 8, 9 and 12.

sacrificing its physical properties, such as physical strength or knot security. Ex. 4 at col. 2, ll. 31-37; col. 2, l. 66. This was also confirmed by Dr. Steckel, one of the inventors of the ‘446 patent. Dr. Steckel stated that the goal was to produce a suture which maintained the strength of Ethibond (an existing suture made of PET), while having the feel and pliability of silk, a substance known to be very pliable and easy to use. Ex. 5 at 103:23-104:17. Whereas the goal of the inventors was to *maintain* the strength of Ethibond, with the acknowledgement that some sacrifice in physical strength may be necessary, FiberWire is the exact opposite. FiberWire makes no sacrifice of physical strength – to the contrary, FiberWire provides superior strength as compared with Ethibond. Ex. 2 at 8.

In February 1992, Ethicon filed the patent application that eventually became the ‘446 patent.

III. THE ‘446 PATENT AND PROSECUTION HISTORY

The specification begins with a summary of prior suture development, explaining that multi-filament braided sutures were developed to improve suture pliability compared to monofilament, unbraided sutures. Ex. 4 at col. 1, ll. 5-25. The specification cautioned, however, that mechanisms, *such as coating*, will adversely affect braid mobility. The specification explains that “the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid.” Ex. 4 at col. 1, ll. 26-29. The first example presented is coating, which “improve[s] handling properties,” but at the expense of braid pliability. Ex. 4 at col. 1, ll. 29-31.

The specification explains that the past attempts in the prior art “have overlooked the importance of fiber-fiber friction and its impact of fiber mobility and braid pliability.” Ex. 4 at col. 2, ll. 14-17. The specification suggests that while a braid made entirely of “highly lubricious polymers” can be used to make a highly pliable braid, such a braid “will be relatively weak and

unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.” Ex. 4 at col. 2, ll. 22-28. This theme that lubricious polymers are too weak for suture usage is repeated when the specification explains that a “volume fraction of lubricating yarns . . . above 80% may adversely affect the overall strength of the braid.” Ex. 4 at col. 4, ll. 50-54.

The specification then explains that the proposed solution is to have a suture comprised of a heterogeneous braid made of two different fiber forming materials which exhibits “improved pliability² and handling properties³ . . . without appreciably sacrificing” [the suture’s] physical properties,” (Ex. 4 at col. 2, lines 31-37), namely its “physical strength and knot security.” Ex. 4 at col. 2, l. 66. This proposed solution is repeated throughout the specification. Ex. 4 at col. 2, ll. 62-66; col. 6, ll. 7-8.

The ‘446 patent relies heavily on what is called the “rule of mixtures” to attempt to demonstrate that this combination is an improvement in the art. Ex. 4 at col. 8, ll. 22, 35 and 38. The point made by the inventors is that gains in pliability and handleability by using the combination of highly pliable and lubricious, but relatively weak, materials with a stronger material outweighs the loss of suture strength.

The specification also discusses the use of coating. It explains that coating, if desired, can be added “to further improve the handleability and knot tiedown performance of the braid. It also explains that if the braid “possesses a significant [amount] of the lubricious yarns, the conventional coating may be eliminated saving expense as well as the associated braid stiffening.” Ex. 4 at col. 6, ll. 5-17.

² The ‘446 patent specifically refers to “pliability” in connection with “resistance to bending,” (Ex.4 at col. 1, ll., 11-15, 24) and “bending rigidity,” (Ex. 4 at col. 6, ll. 44-45, col. 8, Table, ll. 44-46), which are the inverse of pliability.

³ One handling property specifically identified in the patent is “knot tie down.” Ex. 4 at col. 6., ll. 7-8.

In short, the specification teaches several things. First, highly pliable and lubricious yarns are too weak to use alone; that is, the suture would break. Second, using two different materials braided together is designed to improve the handleability and pliability aspects of a suture without significantly hurting the overall braid strength. Third, while adding coating to a braid is helpful for knot tie down and other handleability characteristics, it creates problems with pliability as well as added costs. The use of coating can be avoided, and the downsides it brings can be eliminated if a sufficient amount of the lubricious material is used.

Seven polymers (PTFE, FEP, PFA, PVDF, PETFE, PP and PE) are identified as the yarns that are included for lubricity so as to improve the overall pliability of the braid. Ex. 4 at col. 4, ll. 11-27. Three materials, PET, nylon and aramid, are identified as the ones that could be used for improving the strength of the braid. Ex. 4 at col. 4, ll. 35-40. Notably, the term PE is never associated with the “strength” yarns. This dichotomy, between lubricious polymers for improving overall pliability and polymers added for improving the strength of the braid, is carried into the claims.

Claim 1 of the ‘446 patent is to a surgical suture “consisting essentially of” a heterogeneous braid of a first and second set of yarns in a sterilized and braided construction. Claim 1 further defines the first set of yarns as one of PTFE, FEP, PFA, PVDF, PETFE, PP and PE – the same materials identified in the specification as being pliable and lubricious. The claim defines the second set of yarns as one of PET, nylon and aramid – the same materials identified in the specification as being added for improving the strength of the braid.⁴

As the application for the ‘446 patent was originally filed, there were two sets of claims – one set for heterogeneous braids and a second set for surgical sutures made from

⁴ Since the other asserted claims ultimately are dependent on claim 1 – that is, they have every limitation of claim 1 plus additional limitations – they include the limitations discussed above.

heterogeneous braids. Ex. 6 at 18-20. Early on, Ethicon was required to elect which set of claims it wanted to prosecute. The election was required because the patent examiner observed that they were distinct sets of claims where one set – the heterogeneous braid claims – were an intermediate product that could be used to make surgical sutures (the second set of claims) as well as other products. Ex. 7 at 2. Ethicon elected to pursue the surgical suture claims. Ex. 7. As originally filed, the first suture claim was very broad. It required only that the sterilized suture be comprised of two dissimilar yarns in direct intertwining contact. The specific materials were not part of the claim and it did not include the “consisting essentially of” limitation. Ex. 6 at 18-20.

In the first Office Action, the examiner rejected the suture claims based on U.K. patent application no. 2,218312A to Burgess (“the Burgess application”) (Ex. 8). The Burgess application disclosed a fishing line made of a heterogeneous braid where the braid was made of UHMWPE⁵ and either nylon or polyester. Ex. 8. The examiner rejected the suture claims, explaining that the requirements for fishing line were similar to those of suture. Ex. 7 at 4.

In distinguishing the ‘446 patent from the Burgess application, Ethicon responded that because of its braided construction, “the fishing line of Burgess would have poor knot strength properties.” [Emphasis in original.] Ethicon explained that the Burgess braid combination would have poor knot strength properties because it included UHMWPE. Ethicon stated that UHMWPE “gives the line minimal stretchability.” [Emphasis in original.] Ex. 9 at 2. Ethicon further explained that “although this thread has great strength properties, it suffers from low elongation and, in turn, poor knot strength properties.” [Emphasis in original.] Ethicon concluded that, as a result of the different requirements of fishing line and suture, one should not look to the fishing line art. But Ethicon went a step further. Ethicon also told the Patent Office

⁵ The Burgess application uses the term high tensile polythene, the European term for UHMWPE.

that “[e]ven if one were to look to the fishing line art [the UHMWPE/polyester or nylon combination – the fishing line are presented by the Burgess application], one would inevitably design an unacceptable suture.” Ex. 9 at 3-4. In other words, Ethicon argued that the braid combination disclosed in Burgess – UHMWPE and polyester or nylon – was not an acceptable combination for a suture. Ethicon argued that it was not acceptable because the attributes of UHMWPE were not what one would want in a suture, a position that was crucial in overcoming the examiner’s rejection.

Later during prosecution, Ethicon made two pertinent amendments to the claims. First, it abandoned the broad claims that required only that that braid be made of two dissimilar materials. Ex. 10 at 1. The allowed claims were limited to what is known as “Markush groups,” where the dissimilar materials had to be from the group of specifically-named materials.⁶ In the allowed claims, the first set of yarns were from a group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE. The second set of yarns were from the group consisting of PET, nylon and aramid. Ex. 10 at 1.

Second, the preamble of the claims was amended to change the term “comprising” to “consisting essentially of.” Ex. 10 at 1. This amendment served to significantly narrow the claims. “Comprising” is an open term; infringement is shown as long as the accused device has every limitation of the claims; infringement is not avoided if the accused device has other additional materials. *See, e.g., Free Motion Fitness, Inc. v. Cybex Intern, Inc.*, 423 F.3d 1343, 1353 (Fed. Cir. 2005). “Consisting essentially of” is not an open term. Infringement is avoided if the accused device contains additional ingredients that materially affect the basic and novel characteristics of the claimed invention. *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003).

⁶ A Markush group is one in which the substances grouped are related in some way. *See, e.g.* Manual of Patent Examining Procedure at § 2173.05(h).

IV. LEGAL STANDARDS FOR CLAIM CONSTRUCTION

In a patent infringement case, the court has the “power and obligation to construe as a matter of law the meaning of language used in the patent claim.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996). In affirming this decision, the Supreme Court held “that the construction of a patent, including terms of art within its claims, is exclusively within the province of the court.” *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). “As a general rule, patent claims must be interpreted to sustain their validity if possible.” *Quantum Corp. v. Rodime PLC*, 65 F.3d 1577, 1584 (Fed. Cir. 1995).

The scope of any patent’s protection is defined by its patent claims. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). The first step in any infringement analysis is to determine a patent claims’ meaning and scope. *Markman*, 52 F.3d at 976-977.

In *Phillips*, the *en banc* Federal Circuit endorsed the uncontroversial maxim that the words of a claim are generally given their ordinary and customary meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention. *Phillips*, 415 F.3d at 1313. The court, however, heard the case *en banc* to resolve a dispute regarding two competing methodologies on how to accomplish the task. In its decision, the Federal Circuit endorsed the approach that started the claim construction analysis with the intrinsic evidence - the claims, the written specification and, if appropriate, the prosecution history - rather than the approach enunciated in *Texas Digital Systems, Inc. v. Telegenix, Inc.*, 308 F.2d 1193 (Fed. Cir. 2002), which began the analysis with dictionary definitions and only permitted consideration of the specification and prosecution history for a limited purpose.

In *Phillips*, the *en banc* Federal Circuit emphasized that a disputed claim term can never be viewed in a vacuum, but rather must always be interpreted in the context of the written description and the prosecution history. *Phillips*, 415 F.3d at 1313. The court reiterated its prior

holding from *Vitronics Corp v. Conceptronic, Inc.*, 90 F.3d 1576 (Fed. Cir. 1996), that “the specification is always highly relevant to the claim construction analysis . . . and that it is the single best guide to the meaning of a disputed term.” *Id.* at 1582. The court also stressed the public notice function of patents. It cautioned that undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of “the indisputable public records consisting of the claims, the specification and the prosecution history.” *Phillips*, 415 F.3d at 1319. After discussing the statutory basis for the specification’s importance, the Federal Circuit concluded:

Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.

Phillips, 415 F.3d at 1316, quoting *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

The Federal Circuit approved the use of the prosecution history, also part of the intrinsic evidence, in the claim construction analysis. The court observed that the prosecution history can provide evidence of how the PTO and the inventor understood the patent and that like the specification, the prosecution history was created by the patentee in attempting to explain and obtain the patent. *Phillips*, 415 F.3d at 1317.

While the Federal Circuit held that extrinsic evidence, including expert and inventor testimony, dictionaries, and learned treatises, could be used, the court also held that such evidence “is ‘less significant than the intrinsic record in determining the legally operative meaning of claim language.’” *Id.* at 1317 quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388

F.3d 858, 862 (Fed. Cir. 2004), quoting *Vanderlande Indus. Nederland BV v. Int’l Trade Comm’n*, 366 F.3d 1316, 1318 (Fed. Cir. 2004).⁷

The Federal Circuit was critical of the *Texas Digital* approach and was particularly cautious about the use of dictionary definitions, stating that “[h]eavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term . . . into the meaning of the term in the abstract” and out of its proper context. *Id.* at 1321. The use of dictionary definitions can be troublesome because the applicant “did not create the dictionary to describe the invention” and thus, “there may be a disconnect between the patentee’s responsibility to describe and claim his invention, and the dictionary editors’ objective of aggregating all possible definitions for particular words.” *Id.* at 1321.

Unlike the phrase “comprising,” the phrase “consisting essentially of” in a patent claim is not an open term. Infringement is avoided if the accused device contains additional ingredients that materially affect the basic and novel characteristics of the claimed invention. *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003). To determine the basic and novel characteristics, one need look no further than the patent specification. *Id.*

V. INTERPRETATION OF DISPUTED CLAIM TERMS

DePuy Mitek asserts infringement of independent claim 1 and dependent claims 2, 8, 9 and 12. Claim 1 is as follows:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a

⁷ The court explained that there were several reasons why extrinsic evidence was less reliable than intrinsic evidence. Among other things, it does not have the virtue of being created at the time of prosecution for the purpose of explaining the patent’s scope and meaning, such evidence may not be written for a person of ordinary skill, it can be biased because it is created at the time of and for the purpose of litigation, extrinsic evidence is boundless and each party in litigation will naturally choose the evidence most favorable to its cause and extrinsic evidence poses that it will be used to change the meaning expressed in the public record and thus undermine the public notice function of patents. *Phillips*, 415 F.3d at 1319.

sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

The parties submit for the Court's construction the two disputed terms which appear in all of the asserted claims of the '446 patent.⁸ These two terms, highlighted above, are "PE" and "consisting essentially of," including an identity of the "basic and novel characteristics of the claimed invention."⁹

A. "PE"

Claim Term	Construction
PE	General purpose polyethylene.

One of the principal issues in this case is whether the term PE, as it appears in the asserted claims of the '446 patent, includes UHMWPE, the specialized polymer that provides FiberWire® suture with its superior strength. It should come as no surprise that DePuy Mitek seeks to have the term "PE" construed such that it includes UHMWPE. As we show below, DePuy Mitek can come to that conclusion by relying almost exclusively on dictionary definitions

⁸ Since the terms appear in the independent claim, they are also part of the dependent claims because a dependent claim includes all the limitations of the independent claim plus additional limitations. *See, e.g. Robotic Vision Sys., Inc. v. View Engineering, Inc.*, 189 F.3d 1370, 1376 (Fed. Cir. 1999).

⁹ The parties agree on the construction of the other two claim terms requiring construction. Specifically, the parties agree that the term "direct intertwining contact," means "the mechanical interlocking or weaving of the individual yarns that make up the suture braid." The parties also agree that the term "volume fraction of the first set of yarns in the braided sheath and core" means "the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross-sectional area of all the yarns in the surgical suture."

and by essentially ignoring the specification and prosecution history of the '446 patent, the same approach rejected by the *en banc* Federal Circuit in *Phillips*.

Defendants, on the other hand, believe the term "PE" in the claims refers to general purpose PE which excludes UHMWPE. As explained below, a proper review of the specification and prosecution history -- the precise approach endorsed by the Federal Circuit in *Phillips*, 415 F.3d at 1313 -- leaves no doubt that the applicants did not believe that UHMWPE is a material that falls within its invention and the meaning of the term "PE."

PE is one of the seven polymers listed in the first set of yarns of claim 1. The specification describes these same seven polymers as "lubricating yarns to improve the overall pliability" of the braid. Ex. 4 at col. 4, ll. 11-27. This theme is repeated throughout the specification. The specification unambiguously states that a braid made solely of "highly lubricious yarns" will result in "a highly pliable braid." Ex. 4 at col. 2, ll. 22-24. Likewise, the examples given in the patent demonstrate that a lubricious yarn is highly pliable and adds more pliability to the braid than expected. Ex. 4 at col. 7, ll. 26-35, 54-64; col. 8, ll. 36-49.

This pliability description is the polar opposite of UHMWPE. The evidence in this case indisputably establishes that UHMWPE is stiff and *not* pliable. DePuy Mitek's own expert, Dr. Brookstein, acknowledged this fact in his report. Ex. 11 at ¶ 56. The stated purpose in the patent is for the first set of yarns (including "PE") to provide improved pliability. It simply makes no sense to construe the term "PE" to include a product that makes the suture too stiff -- the exact *opposite* effect as that described in the patent.

But there is much more. The specification teaches that while a braid made entirely of lubricious materials (such as the materials in the first group) would make a highly pliable braid, such a braid "will be relatively weak and unusable." Ex. 4 at col. 2, ll. 22-25. This is why the specification teaches that there is a tradeoff between braid strength and pliability -- the lubricious

materials have good pliability, but poor braid strength. The notion that the lubricious polymers are too weak for suture usage is repeated when the specification cautions against using more than about 80% of the lubricious yarns because such usage “may adversely affect the overall strength of the braid.” Ex. 4 at col. 4, ll. 50-54.

The description of the first and second groups of yarns continues this theme. The specification teaches that a yarn from the second group of yarns needs to be added “to provide improved strength to the heterogeneous braid.” Ex. 4 at col. 4, ll. 33-36. The reason that a “strength” yarn is needed is obvious -- the “pliable” yarns of the first set are too weak, just as the specification teaches. Ex. 4 at col. 2, ll. 22-25; col. 4, ll. 52-54.¹⁰

Once again, it would make no sense to include UHMWPE within the meaning of “PE. Unlike general purpose PE, UHMWPE is an incredibly strong material, one of the strongest materials known to man. It simply is not the kind of material which must be balanced against strong materials to achieve an acceptable suture. It simply makes no sense to include such a strong material where the patent teaches the exact opposite.

Notably, while PE is included in the group of seven lubricious materials identified for improving pliability, PE is *not* included in the group of materials identified for strength. Nor is the term PE ever associated with the “strength” yarns in the specification of the ‘446 patent. If PE included UHMWPE, one would have expected to see “PE” appear in the strength list. At a bare minimum, one would have expected to see *some* mention in the patent the “PE” could also

¹⁰ That the ‘446 patent considers the lubricous materials to be relatively weak is also confirmed by the tests described in the specification. For example, the Table depicts results for a multifilament braid made entirely (*i.e.*, 100 %) of a lubricious first fiber-forming material (*i.e.* CONTROL II made up of 100% PTFE). This braid was the weakest of the four braids tested, which is entirely consistent with the teachings of the specification.

Moreover, the ‘446 patent relies heavily on what it calls the “rule of mixtures” to explain that gains in pliability and handleability by using the combination of lubricious, but relatively weak materials (*i.e.* the seven lubricious polymers) with a stronger material (*i.e.*, the three strength materials) outweighs the loss of suture strength realized due to the lubricious materials.

impart strength. This is particularly true in light of the fact that Ethicon and the inventors knew that UHMWPE has great strength. Inventor Steckel testified that he knew during the development work that lead to the '446 patent that UHMWPE had great strength. Ex. 5 at 190:12-191:3. Likewise, when responding to an office action during prosecution, Ethicon acknowledged that UHMWPE "has great strength properties." Ex. 9 at 2. There is a plain and simple reason that there is absolutely no mention of "PE" having strength; UHMWPE was the furthest thing from the applicants' minds when they described their invention.

As the Federal Circuit has instructed on several occasions, [t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction; *Phillips*, 415 F.3d at 1316; *Renishaw*, 158 F.3d at 1250. Here, the interpretation of "PE" that naturally aligns with the patent's description of the invention is general purpose PE and *not* UHMWPE.

If there were any doubt – and there is none – it is categorically removed by a review of Ethicon's arguments against UHMWPE in the prosecution history, which is part of the intrinsic evidence that should be consulted in determining the meaning of claim terms.

As mentioned above, during prosecution of the '446 patent, the examiner rejected the suture claims based on the Burgess application, which disclosed a fishing line made of a heterogeneous braid where the braid was made of UHMWPE and either nylon or polyester. Ethicon argued the Burgess braid would make a poor suture. In particular, the combination would be poor *because it contained UHMWPE*, a product with "minimal stretchability" and which "suffers from poor elongation." Ex. 9 at 2-3. Ethicon concluded by stating that "[e]ven if one were to look to the fishing line art, *one would inevitably design an unacceptable suture.*" Ex. 9 at 3-4. [Emphasis added.] In other words, Ethicon told the patent examiner, and by extension the public, that the combination disclosed in Burgess – UHMWPE and polyester or

nylon – would *not* make an acceptable suture. And the reason that the combination would be unacceptable was because it contained UHMWPE.

The fact is that UHMPE and general purpose PE are fundamentally very different materials. They are used for different purposes, and one can not be substituted for the other. Ex. 12 at 22. General purpose polyethylene has been around for decades and established itself as a general purpose commodity polymer. Ex. 3 at § 1. Since its introduction in fiber form in 1985, UHMWPE, to the contrary, has been considered a specialized high performance product. Ex. 3 at § 1. General purpose polyethylene and UHMWPE are simply not substitutes for each other. Ex. 12 at 22. Moreover, the key structural characteristics – molecular weight and molecular structure – of UHMWPE are very different than that of general purpose PE. Ex. 3 at § 2. UHMWPE has a molecular weight in the range of 1 to 5 million, whereas general purpose PE has a molecular weight in the range of 50,000 to several hundred thousand. UHMWPE also exhibits a much higher degree of crystalline orientation and crystalline content as compared with general purpose PE. These stark differences in molecular structure are the basis for UHMWPE's superior strength characteristics. Ex. 3 at § 2.

Despite all of the above, and contrary to the clear teachings of the '446 patent, DePuy Mitek has asserted that the term "PE" means "all types of polyethylene (PE) including ultra high molecular weight polyethylene." Ex. 11 at ¶ 27; Ex. 13 at ¶ 28.

The only way DePuy Mitek comes to this conclusion is by essentially ignoring the clear teachings of its own specification. DePuy Mitek must ignore the specification since it reveals the truth about what the term PE means in the context of the '446 patent – i.e., that it includes general purpose polyethylene, but does not include UHMWPE. Even DePuy Mitek's own expert initially admitted this. Dr. Hermes' own first impression when reading the '446

patent was that it “seem[ed] to teach away from UHMWPE.” Ex. 14; Ex. 15 at 335:12-336:15. Dr. Hermes’ first impression was entirely correct.

Undaunted by the truth, however, DePuy Mitek forges ahead and seeks to improperly construe the term PE through the use of extrinsic evidence in the form of technical treatises that take the claim terms completely out of the context in which they were written and intended -- the *Texas Digital* approach. As described above, however, this approach was resoundingly rejected by the Federal Circuit in the landmark *Phillips* decision.

The *Phillips* court warned, “[h]eavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term . . . into the meaning of the term in the abstract” and out of its proper context. *Id.* at 1321. The court further reasoned that the use of dictionary definitions can be troublesome because the applicant “did not create the dictionary to describe the invention” and thus, “there may be a disconnect between the patentee’s responsibility to describe and claim his invention, and the dictionary editors’ objective of aggregating all possible definitions for particular words.” *Id.* at 1321.

The “disconnect” that troubled the Federal Circuit is the very basis for DePuy Mitek’s claim construction. For example, DePuy Mitek’s expert, Dr. Hermes, points to a technical treatise – entirely divorced from the context of the ‘446 patent – as supporting the assertion that the term “PE,” as it appears in the ‘446 patent, is the generic name for all types of PE, including UHMWPE. The same treatise Dr. Hermes relies upon, however, expresses the very same concerns stated by the *Phillips* court 18 years later. The treatise states that so-called source-based nomenclatures have “serious deficiencies,” and predicts that as a result there will be a gradual shift “away from starting materials and toward the structure of the macromolecules.” Ex. 16 at 193. When confronted with this concern and prediction expressed in the same treatise he relied upon, Dr. Hermes could only state that that was the opinions of the authors and that he

did not have enough knowledge to disagree with those authors. Ex. 15 at 246:25 – 247:19. This is the approach the *Phillips* court warned about.

As made clear by the entirety of the intrinsic evidence – *i.e.*, the specification and the prosecution history – when the inventors used the term “PE,” they intended to mean general purpose polyethylene and not UHMWPE. Even DePuy Mitek’s own expert, on his initial reading of the patent, recognized that the specification “seems to teach away from UHMWPE.” For all the above reasons, Defendants’ proposed construction should be adopted.

B. “Consisting essentially of”

Claim Term	Construction
Consisting essentially of	<p>i) The claimed surgical suture excludes additional ingredients that materially affect the basic and novel characteristics of the claimed invention.</p> <p>ii) The basic and novel characteristics of the claimed invention are a suture having two dissimilar yarns (from the list identified in the claims) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties.</p>

As described above, it is well settled that the transitional phrase “consisting essentially of,” as it appears in the asserted claims of the ‘446 patent, is construed to mean that infringement is avoided if the accused device contains additional ingredients that materially affect the basic and novel characteristics of the claimed invention. *AK Steel Corp.*, 344 F.3d at 1239. The parties do not appear to dispute this basic principle. The parties do dispute, however, the identity of the “basic and novel characteristics of the claimed invention.” As the Federal Circuit stated in *AK Steel*, one need look no further than the specification in order to make that determination. *Id.* at 1239. This case is no different.

In making this determination, the focus, of course, starts with the claims because the claims define the scope of the protected invention. Here, the claims are not merely to two dissimilar materials braided together,¹¹ but rather to the two groups with specific materials for each group (PTFE, FEP, PFA, PVDF, PETFE, PP and PE for the first group; PET, nylon and aramid for the second group). Thus, the issue is what does the specification attribute as the basic and novel characteristics for a suture braid made of these specific materials.

Focusing on the purpose of the recited materials, the specification of the '446 patent identifies the basic and novel characteristics of the claimed invention as being a suture having two dissimilar yarns (of the materials claimed) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. This concept is repeated throughout the specification, both when referring to the essential idea behind the patent and when discussing the recited materials directly. Ex. 4 at col. 2, ll. 29 – 37; ll. 62 – 66; col. 4, ll. 11-40; col. 6, ll. 7 – 8. Matthew Goodwin, the attorney who prosecuted the application for Ethicon, also confirmed this was the basic aspect of the invention. Ex. 17 at 110:14-20.¹²

As previously mentioned, the specification describes that there is a tradeoff between braid strength and pliability. In the specification, this tradeoff is advantageous because the gains achieved in pliability and handleability outweighs the loss of suture strength resulting from combining a weaker, pliable material with the stronger material. According to the specification,

¹¹ As originally filed, the application included a broad claim of two dissimilar fibers braided together without specifying any specific materials. Ex. 6. That broad claim, however, was abandoned during prosecution. Ex. 10 at 1. Language in the patent specification that relates to this broad abandoned claim cannot serve as a basis for determining the basic and novel characteristics of the narrower claims.

¹² This is also consistent with Dr. Steckel's testimony that the goal was to improve the handleability and pliability to make the suture more like silk while maintaining the strength of the existing Ethibond polyester suture. Ex. 5 at 103:23-104:17.

the resulting suture is one with improved handleability and pliability performance without significantly sacrificing its physical properties. Ex. 4 at col. 2, ll. 31-37; col. 2, l. 66.

Improved pliability and handleability on the one hand, with a minimal reduction in strength on the other hand are the characteristics attributed to the specific materials recited in the claims. The first set of yarns is included to improve pliability and surface lubricity. But because such yarns are weak, a strength component is added by a yarn of the second group. Ex. 4 at col. 2, ll. 22-25; col. 4, ll. 11-40.

Accordingly, by reviewing the specification, it becomes evident that the basic and novel characteristics of the claimed invention are a suture having two dissimilar yarns (from the list identified in the claims) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. We ask that the Court adopt this construction.

VI. CONCLUSION

For all the foregoing reasons, defendants request that the Court adopt the claim interpretations contained herein.

Dated: August 11, 2006

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Defendants Arthrex, Inc.'s and Pearsalls, Ltd.'s Opening Brief on Claim Construction was served, via the Court's email notification system on the following counsel for Plaintiff on the 11th day of August 2006:

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SUBSTITUTE EXHIBIT 15

Deposition of:
Dr. Matthew Hermes, Vol. I

June 27, 2006

Page 1

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
C.A. NO. 04-12457 PBS

COPY

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DePUY-MITEK, INC.,

A Massachusetts Corporation,
Plaintiff,

vs.

ARTHREX, INC.,

A Delaware Corporation,
Defendants.

-----x
DEPOSITION OF DR. MATTHEW HERMES

Philadelphia, Pennsylvania

June 27, 2006

Reported by:

CONSTANCE S. KENT, CSR, RPR

JOB NO.: 350

Deposition of:
Dr. Matthew Hermes, Vol. I

June 27, 2006

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1 clearer source-based names, correct?

2 A. Yes.

3 Q. Okay. Is it your understanding that
4 this document is designed to try and clear up an
5 ambiguity that existed?

6 A. No, it's my understanding that it's a
7 document describing generic source-based
8 nomenclature.

9 Q. What does it mean to you when it says
10 it solves these problems and yields clearer
11 source-based names?

12 A. Whatever problems there were, it's
13 attempting to clear them up. I'm sorry, I'm not
14 familiar with what the specific problems were.

15 Q. But you agree with me this document
16 in 2001 is an attempt to clear up problems that
17 existed on names?

18 A. That's what it says sir, yes.

19 Q. Let's -- let's go to Exhibit 18 if we
20 could, please.

21 A. Indeed.

22 Q. Could you turn to page 193 of this
23 report?

24 A. Yes.

25 Q. Is it correct that this -- this

Deposition of:
Dr. Matthew Hermes, Vol. I

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1 exhibit is saying that there are deficiencies of
2 source-based nomenclature?

3 A. The -- the paragraph beginning the
4 principal deficiency talks in general about a
5 nomenclature problem that has been inherent in
6 defining the names of polymers, yes.

7 Q. And if you look further down the
8 paragraph, doesn't it conclude, the paragraph: The
9 rapid advances now being made in the structural
10 determination of polymers will gradually shift the
11 emphasis of polymer nomenclature away from the
12 starting materials and toward the structure of the
13 macromolecules?

14 A. That's a -- that is the opinion of
15 the authors.

16 Q. Do you have any reason to disagree
17 with the opinions of the authors?

18 A. I don't think I have enough knowledge
19 to disagree with those authors.

20 Having said that, this was published
21 in 1987, 20 years ago, and there's no -- there's no
22 indication in the field of ethylene and polyethylene
23 that anything of that kind is going on these days.
24 Polyethylene is still polyethylene, and the -- the
25 structural details do not appear in the source-based

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1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS

4 _____ x

5 DePUY-MITEK, INC.,

6 A Massachusetts Corporation,

7 Plaintiff,

8 vs.

9 ARTHREX, INC.,

ORIGINAL

10 A Delaware Corporation,

11 Defendants.

12 _____ x

13 DAY 2 OF 2

14 CONTINUED VIDEOTAPED DEPOSITION

15 OF DR. MATTHEW HERMES

16 Philadelphia, Pennsylvania

17 July 25, 2006

18

19

20 Reported by:

21

22 PAMELA HARRISON, RMR, CRR, CSR

23

24

25

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1 your -- you made them the first time you reviewed	01:01:49p
2 the report, if I understood your answer	01:01:51p
3 correctly?	01:01:53p
4 MR. BONELLA: Object to form.	01:01:54p
5 THE WITNESS: I believe so, but	01:01:55p
6 I'm not certain.	01:02:02p
7 BY MR. SABER:	01:02:05p
8 Q. Okay. I want to ask you about near --	01:02:05p
9 on the bottom there you have numbers one, two,	01:02:09p
10 three, and four?	01:02:11p
11 A. Yes, sir.	01:02:12p
12 Q. I want to ask you about number three,	01:02:12p
13 if I could, please. Could you read the first	01:02:14p
14 sentence there, just to make sure that it's --	01:02:19p
15 A. This is my note, Mr. Saber, is that	01:02:22p
16 right?	01:02:24p
17 Q. Yes, sir.	01:02:24p
18 A. You want me to read my note.	01:02:25p
19 Q. Yes, sir. The first sentence.	01:02:27p
20 A. I'll be glad to.	01:02:28p
21 "'446 -- '446 teachings on	01:02:29p
22 offsetting properties of yarn A with yarn B may	01:02:45p
23 seem to teach away from ultra high molecular --	01:02:50p
24 UHMWPE, but the critical principle is mixing	01:02:57p
25 yarns and getting better than accepted	01:03:04p

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		Page 336
1	properties."	01:03:08p
2	Q. When you used the --	01:03:10p
3	A. I'm not finished.	01:03:12p
4	Q. Okay. I'm sorry, sir.	01:03:13p
5	A. It doesn't -- I'm not finished.	01:03:14p
6	"It doesn't LIMIT," in capital	01:03:18p
7	letters, "A, strength, or B, lubricity, just	01:03:20p
8	suggests it."	01:03:27p
9	Q. When you used the nomenclature I think	01:03:27p
10	you said UHMWPE?	01:03:32p
11	A. Yes.	01:03:35p
12	Q. Does that mean ultra high molecular	01:03:35p
13	weight PE?	01:03:37p
14	A. That did mean ultra high molecular	01:03:38p
15	weight polyethylene, yes.	01:03:39p
16	Q. Right. When you wrote at the end, you	01:03:41p
17	said, just suggests it, A, strength, and B,	01:03:46p
18	lubricity, what did you mean by that?	01:03:50p
19	A. I meant -- I meant specifically that	01:03:51p
20	the teachings in the preferred embodiment in	01:03:54p
21	which -- in which the preferred embodiment	01:03:58p
22	mentions the relationship of -- the preferred	01:04:02p
23	embodiment discussing PTFE, that -- in which we	01:04:05p
24	talk about the strength of the braid and the	01:04:11p
25	relationship of strength to the braid, that that	01:04:17p